Federal Court  Cour fédérale

Date: 20120523

Docket: T-1161-07

Citation: 2012 FC 552

BETWEEN:

SANOFI-AVENTIS CANADA INC.,
SCHERING CORPORATION and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

AND BETWEEN

TEVA CANADA LIMITED

Plaintiff by Counterclaim

and

SANOFI-AVENTIS CANADA INC.,
SCHERING CORPORATION and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Defendants by Counterclaim

PUBLIC REASONS FOR JUDGMENT
(Confidential Reasons for Judgment released May 11, 2012)

SNIDER J.

I. Introduction

[1] Teva Canada Limited (Teva), the Plaintiff by Counterclaim in this action, sells a generic version of ramipril – a drug used mainly to treat hypertension – into the Canadian market. Sanofi-Aventis Canada Inc. (Sanofi), one of the Defendants by Counterclaim in this action, holds or has held patent rights to a brand-name version of ramipril – ALTACE.

[2] In spite of the fact that Teva (or its predecessors in interest) received certain regulatory approvals from Health Canada in 2003, it was unable to commence sales of ramipril until May 2, 2007, when it received its Notice of Compliance (NOC) from Health Canada, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *PM (NOC) Regulations* or the *Regulations*). In whole or in part, the delay was caused by the actions of Sanofi, which exercised its rights under the *Regulations* to a statutory stay of the issuance of an NOC to Teva. Teva claims that Sanofi and Sanofi-Aventis Deutschland GmbH (Sanofi Germany) are liable to Teva for the loss it suffered during the period from July 18, 2003 to April 27, 2007, as provided for in s. 8(1) of the *PM (NOC) Regulations*.

[3] Subject to validity issues raised in its pleadings, Sanofi acknowledges and accepts that Teva is entitled to damages under s. 8. However, Sanofi disputes many elements of Teva's claim, including: (a) the relevant dates for computing the loss; and (b) various assumptions and projections built into the assessment of damages.

[4] Sanofi's claim of invalidity of s. 8 of the Regulations was separately argued in a hearing involving this and similar issues in Court File No. T-1357-09 (*Apotex Inc v Sanofi-Aventis, Sanofi-Aventis Deutschland GmbH and Sanofi-Aventis Canada Inc*). Separate Reasons have been rendered in respect of the validity issues (see 2012 FC 551). Moreover, by Order of Prothonotary Milczynski, dated August 15, 2011, all of the claims of Teva with respect to Sanofi Germany have been bifurcated. Thus, these Reasons do not include a consideration of either the invalidity claims of Sanofi or Teva's claims against Sanofi Germany.

[5] My overarching objective is to assess the amount of compensation to be awarded to Teva. Following the teachings of the Court of Appeal in *Apotex Inc v Merck & Co*, 2011 FCA 329 at para 75, 425 NR 279 [*Norfloxacin (FCA)*], this requires that I consider the hypothetical question: What would have happened if Sanofi had not brought an application for prohibition? In other words, I must construct a hypothetical, or "but for", world during a defined period of time in the past in order to determine what share of the ramipril market Teva would have captured if it had been able to sell its generic ramipril. In addition to some of the common issues arising on an assessment of damages, one of the key tasks before me is to examine various provisions of the *PM (NOC) Regulations*. Well-established principles of statutory interpretation will guide me in establishing what I believe to be the correct meaning.

[6] In the reasons that follow, I address the many issues raised by this action. Three of my key conclusions are as follows:

1. The period of liability (the Relevant Period) cannot begin before the date upon which a statutory stay provided for in s. 6 of the *Regulation*s commences and, on the particular facts of this case, a more appropriate commencement date is December 13, 2005. The Relevant Period is therefore December 13, 2005 to April 27, 2007.

2. The Court should have regard to the possibility of multiple market entrants during the Relevant Period, leading to a result, on the facts of this case, that it is more likely than not, that both Apotex Inc. (Apotex) and a generic manufacturer sanctioned by Sanofi (known as an authorized generic, or AG) would have entered the generic ramipril market on or about December 13, 2005.

3. In assessing Teva's damages, no regard should be had to: (a) "lost business value" calculated as of the final day of the Relevant Period and based on future lost profits to Teva; or (b) "duplicate ramp-up".

[7] This case was one of three s. 8 damages actions brought against Sanofi by generic manufacturers with respect to ramipril. This was the first action heard. The second action is *Apotex Inc v Sanofi-Aventis, Sanofi-Aventis Deutschland GmbH and Sanofi-Aventis Canada Inc*. (Court File No. T-1357-09). The trial of that action took place before me after the conclusion of

this trial and has resulted in a decision released concurrently with these Reasons. The third action is *Sanofi-Aventis Canada Inc et al v Laboratoire Riva Inc* (Court File No. T-1201-08). The trial of this third action has yet to take place.

[8] I have set out a brief overview of the many fact and expert witnesses who appeared during the trial and the areas to which they testified in Appendix A. For the experts, I have described the matters in respect of which I found them to be qualified to provide me with their expert opinions. More detailed references to the witnesses' evidence and testimony are contained in the appropriate sections of these Reasons.

II. Contents

[9] To assist the reader, I am including an outline of these Reasons. The paragraph number for the beginning of each noted section is set out below:

III. Issues

[10] In general terms, the assessment of Teva's damages involves five steps:

1. determine the duration of the Relevant Period;

2. determine the overall size of the ramipril market during the Relevant Period (the Ramipril Market);

3. determine the portion of the market that would have been retained by Sanofi and the portion that would have been held by generic manufacturers during the Relevant Period (the Generic Market);

4. determine the portion of the Generic Market that would have been held by Teva (Teva's Lost Volumes); and

5. quantify the damages that would have been suffered by Teva in respect of Teva's Lost Volumes during the Relevant Period (Teva's Net Lost Profits).

[11] In the case before me, these steps require consideration of a number of issues where the parties are in disagreement. These issues are as follows:

1. What is the appropriate period for which losses can be claimed by a second person under s. 8 of the *Regulations*? Given that the parties are agreed that the Relevant Period ends on April 27, 2007, the remaining sub-issues related to the Relevant Period are:

    a. Can the Relevant Period begin on the date when the second person would have received its NOC, even where that event occurred prior to the service of a notice of allegation and imposition of the statutory stay contemplated by the *Regulations*?

b. On the facts of this case, is the appropriate date for the commencement of the Relevant Period:

i) July 18, 2003, when Teva received its drug identification numbers (DINs) for ramipril from Health Canada;

ii) October 14, 2003, the date Health Canada's review of Teva's drug submission was completed and Teva was advised that an NOC would not issue until the requirements of the *Regulations* were met (referred to as the "patent hold" date; see Exhibit 9, Tab 8);

iii) October 31, 2005, the date Sanofi served and filed a Notice of Application in respect of a notice of allegation served by Teva on September 12, 2005, thereby triggering the statutory stay provided for in s. 7(1)(e) of the *Regulations*; or

iv) December 13, 2005, the date of expiry of the '457 Patent, which was the subject of the patent hold referred to in ii) above?

2. What would have been the size of the Ramipril Market over the Relevant Period?

3. How much of the overall Ramipril Market in the Relevant Period would have been captured by the generic participants?

4. What would have been Teva's Lost Volumes during the Relevant Period? Subsidiary to this question are the following sub-issues:

    a. In assessing Sanofi's liability under s. 8, is Teva's compensation to be assessed on the basis that the second person would be the sole generic supplier on the market for the entire Relevant Period? Alternatively, is Sanofi's liability to be assessed on the basis of a single "but for" world which includes all potential generic manufacturers?

    b. What other generics would likely have come to market during the Relevant Period and when? Specifically, would any or all of Apotex, Laboratoire Riva Inc. (Riva) and/or Pharmascience Inc. (Pharmascience or PMS), or an authorized generic have launched during the Relevant Period?

    c. What portion of the Generic Market would Teva have captured during the Relevant Period (i.e. Teva's Lost Volumes)?

5. Based on my finding as to Teva's Lost Volumes, what is Teva's Net Lost Profits, having regard to:

    a. the admissibility of evidence of Teva's "lost business value" and "second ramp-up" as set out in the report of Teva's expert witness, Ms. Suzanne

Loomer, as losses that were not "suffered during the period" as contemplated by s. 8(1) of the *Regulations*;

b. the pricing of Teva's ramipril during the Relevant Period, having regard to the provincial formularies;

c. likely trade spend (including discounts and allowances) that would have been paid by Teva to pharmacists to stock Teva's ramipril;

d. likely price of the active pharmaceutical ingredient (API) for ramipril;

e. the reasonableness and quantification of any indirect losses, such as the loss of sales of other products; and

f. the appropriate calculation of pre-judgment interest?

6. Is a second person entitled to recover under s. 8 of the *Regulations* for lost sales that would have been made as a result of prescriptions that were aimed at unapproved indications?

IV. Essential Background

[12] This action involves a complex statutory framework and a complicated set of facts. For ease of reference, I attempt to summarize the statutory framework and the most relevant (and undisputed) background facts related to the corporate identity of the parties, Sanofi's patents for ALTACE, and Teva's regulatory and litigation history on ramipril.

A. *Statutory framework under the PM (NOC) Regulations*

[13] This action arises solely out of the operation of the *PM (NOC) Regulations*. Quite simply, Teva was kept off the market for a period of time by the actions of Sanofi that were ultimately found to be unsustainable. In his decision in *Apotex Inc v Merck & Co*, 2008 FC 1185 at paras 35-51, [2009] 3 FCR 234 [*Alendronate (FC)*], Justice Hughes provides a comprehensive history and rationale of the *Regulations* generally, and s. 8 in particular. Although the decision in *Alendronate (FC)* was overturned in part by the Court of Appeal in *Apotex Inc v Merck & Co*, 2009 FCA 187, [2010] 2 FCR 389, rev'g 2008 FC 1185, leave to appeal to SCC refused [2009] SCCA No 347 [*Alendronate (FCA)*], Justice Hughes's description of the *PM (NOC) Regulations* remains a valuable tool. Rather than restate this history, I commend the identified passages to the reader.

[14] The damages suffered by Teva are statutory in that they arise only because of the operation of s. 8 of the *PM (NOC) Regulations*. The liability of Sanofi, in this case, is better understood if s. 8 is examined in the context of the entire statutory scheme. I will provide a brief overview of the statutory scheme that gives rise to Teva's claim. Ms. Anne Bowes, the director

of the Office of Patented Medicines and Liaison of Health Canada, was helpful in explaining the operation of the applicable regulations and policies engaged on the facts of this case.

[15] Before a pharmaceutical company can market a prescription drug in Canada, it must comply with the provisions of the *Food and Drug Regulations*, CRC, c 870 [*F&D Regulations*] to obtain a Notice of Compliance (NOC). Section C.08.002 of the *F&D Regulations* provides, in part that:

(1) No person shall sell or advertise a new drug unless	(1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :
(*a*) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;	*a*) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle, une présentation de drogue nouvelle pour usage exceptionnel, une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel que celui-ci juge acceptable;
(*b*) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission;	*b*) le ministre a délivré au fabricant de la drogue nouvelle, en application des articles C.08.004 ou C.08.004.01, un avis de conformité relativement à la présentation;

[16] As provided for in s. C.08.002(1)(a) of the *F&D Regulations*, anyone who wishes to sell a drug in Canada must submit to the Minister of Health (through Health Canada), either a new drug submission (NDS) or an abbreviated new drug submission (ANDS). An NDS is filed by an innovative drug company, or "first person", seeking approval to market a new drug product. In contrast and in very general terms, an ANDS is filed by a generic manufacturer, or "second person", that wishes to market a generic version of a drug that has already been approved. The second person may rely on much of the technical, health and safety information originally filed as part of the NDS by the first person. In other words, it may compare its drug with, or make reference to, a brand name drug (*F&D Regulations*, above at s. C.08.002.1.(1)).

[17] An essential element of the regulatory scheme is the "Patent Register". The *PM (NOC) Regulations* allow an innovator who has filed an NDS or a supplement to a new drug submission (SNDS) to submit a list of the associated patents to the Minister of Health (Minister) for inclusion on the register of patents (Patent Register or Register) (s. 4(1)). The *Regulations* require that the Minister maintain a register of all listed patents (s. 3(2)). Subsections 4(2) and (3) of the *Regulations* describe the eligibility requirements for listing.

[18] If a patent is listed on the Patent Register, s. 5 of the *PM (NOC) Regulations* provides that the second person, with respect to each patent on the Patent Register, must, in its application for an NOC:

- state that it accepts that the NOC will not issue until the patent expires (s. 5(1)(a)); or

- allege that:
    - the first person is not the patentee or licensee of the listed patent (s. 5(1)(b)(i));
    - the patent has expired (s. 5(1)(b)(ii));
    - the patent is not valid (s. 5(1)(b)(iii)); or
    - the second person will not infringe the listed patent (s. 5(1)(b)(iv)).

The second person identifies its election on the Form V submitted with its application. As accepted by everyone, the election can be changed at any time.

[19] If a second person alleges that an NOC should issue in spite of the listed patents, it must serve a notice of allegation on the first person (*Regulations*, above at s. 5(3)). The first person may, within 45 days after service, apply to the Federal Court for an order prohibiting the Minister from issuing an NOC until the expiration of a patent that is the subject of the notice of allegation (*Regulations*, above at s. 6(1)). This action triggers a “statutory stay” (also referred to as an “automatic stay”) which remains in place for up to 24 months (*Regulations*, above at s. 7(1)(e)).

[20] The specific circumstances in which the Minister may not issue an NOC are dealt with in s. 7(1) of the *PM (NOC) Regulations*. Of relevance to these proceedings, the Minister may not issue an NOC to a second person before the latest of:

- the day on which the second person complies with the requirements of s. 5 (s. 7(1)(b));
- the expiration of any patent on the Register that is not the subject of an allegation (s. 7(1)(c));
- the expiration of 45 days after the receipt of proof of service of a notice of allegation under s. 5(3)(a) in respect of any patent on the Register (s. 7(1)(d));
- the expiration of 24 months after the receipt of proof of the making of any application under s. 6(1) (s. 7(1)(e)); and
- the expiration of any patent that is the subject of an order of prohibition pursuant to s. 6(1) (s. 7(1)(f)).

[21] Regardless of the election made by a second person under s. 5(1) of the *Regulations*, Health Canada will process the application for all health and safety considerations and will assign a DIN (*F&D Regulations*, above at s. C.01.014.2(1)). However, no NOC will issue until the relevant patents on the Register either expire or have been addressed through the *PM (NOC)*

Regulations process. The day on which a generic drug product would have otherwise received its NOC is called the “patent hold date”.

[22] At that stage, except for the completion of any proceedings under the *Regulations*, the NOC is ready for issuance. As stated by Ms. Bowes “. . . the NOC itself, full package is in the file cabinet waiting for its turn to go back out the door”.

[23] As noted, the service of a Notice of Application triggers the statutory stay. After hearing the application, the court may dispose of the innovator’s prohibition application in several ways. First, if the court finds that none of the generic’s allegations are justified, it must issue an order prohibiting the Minister from issuing an NOC to the generic (*Regulations*, above at s. 6(2)). In that case, the generic will not receive its NOC until patent expiry (unless the decision of the Federal Court is overturned on appeal).

[24] Alternatively, the court may dismiss the innovator’s application in whole or in part (*Regulations*, above at s. 6(5)), or the application may be withdrawn or discontinued by the first person. If an application is dismissed, withdrawn, or discontinued, the generic will receive its NOC almost immediately. Most relevant to this case, the generic will also be able to invoke s. 8 of the *Regulations*. Section 8 allows a generic to bring an action against an innovator for compensation for the period it was kept off the market as a result of the innovator’s unsuccessful prohibition application.

[25] The full text of s. 8 is set out below:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period	**8.** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :
(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that	*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :
(i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or	(i) soit que la date attestée est devancée en raison de l'application de la *Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique)*, chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,
(ii) a date other than the certified date is more appropriate; and	(ii) soit qu'une date autre que la date attestée est plus appropriée;
(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	*b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de
(2) A second person may, by action against a first person,	

apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.

(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

(6) The Minister is not liable for damages under this section.

l'annulation de l'ordonnance.

(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action en contrefaçon du brevet visé par la demande.

(4) Lorsque le tribunal enjoint à la première personne de verser à la seconde personne une indemnité pour la perte visée au paragraphe (1), il peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts à l'égard de cette perte.

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

(6) Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

[26] This then is the context for these Reasons.

B. *Corporate background*

[27] The Plaintiff by Counterclaim, Teva, is an Ontario corporation and a manufacturer, vendor, and distributor of pharmaceutical products. Prior to February 16, 2010, Teva was known as Novopharm Limited (Novopharm). Teva's Israeli parent company, Teva Pharmaceutical Industries (Teva Israel), purchased Novopharm in April of 2000. Teva amalgamated with Ratiopharm Canada Inc. and Ratiopharm Inc. (ratiopharm) on August 10, 2010.

[28] Throughout these Reasons for Judgment, the name "Teva" will be used to refer to either Teva or Novopharm, unless the context requires greater specificity. Teva's ramipril product, however, will be called "Novo-ramipril", as that was the product's initial name.

[29] The Defendant by Counterclaim, Sanofi, is a Quebec corporation and a manufacturer, vendor and distributor of pharmaceutical products. Sanofi has several corporate predecessors, including Hoechst Marion Roussel Canada Inc., Rhône-Poulenc Rorer Canada Inc., and Aventis Pharma Inc. The name "Sanofi" will be used in these Reasons to refer to Sanofi and its corporate predecessors, unless the context suggests otherwise.

C. *Ramipril patents*

[30] Sanofi, either as patentee or licensee, holds the rights to a series of Canadian patents that include claims to ramipril or its uses. The initial patent was Canadian Patent No. 1,187,087 (the '087 Patent) – a product-by-process patent for ramipril – issued May 14, 1985. The '087 Patent was originally set to expire on May 14, 2002, after 17 years of patent protection. Sanofi, in efforts to extend patent protection for ramipril, proceeded to obtain a further series of patents and to protect those patents through listings on the Patent Register. Sanofi describes these subsequent patents and the measures it took, through litigation under the *PM (NOC) Regulations*, as "product life cycle management". Others – including generic manufacturers – have referred to the subsequent patents as "evergreening".

[31] The following chart describes the subsequent patents involving ramipril or its uses and identifies when each patent was listed on the Patent Register:

Canadian Patent No.	**Issue Date**	**Patent Register Listing**	**Subject Matter/Indications**
1,246,457 (the '457 Patent)	December 13, 1988 (expired December 13, 2005)	February 21, 2001	Ramipril for the treatment of cardiac insufficiency
1,341,206 (the '206 Patent)	March 20, 2001	April 11, 2001	The product ramipril
2,055,948 (the '948 Patent)	November 12, 2002	June 25, 2004	Use of ramipril together with a calcium antagonist for the prevention and treatment of proteinuria
2,023,089 (the '089 Patent)	January 14, 2003	November 1, 2003	Use of ramipril in the treatment of cardiac and vascular hypertrophy and hyperplasia
2,382,549 (the '549 Patent)	March 15, 2005	March 17, 2005	Use of ramipril in the prevention of cardiovascular events.

Canadian Patent No.	Issue Date	Patent Register Listing	Subject Matter/Indications
2,382,387 (the '387 Patent)	June 21, 2005	June 28, 2005	Use of ramipril for the prevention of stroke, diabetes and/or congestive heart failure.

[32] The '549 and '387 Patents are referred to, collectively, as the HOPE Patents after the Heart Outcomes Prevention Evaluation study (HOPE study), discussed in more detail below.

D. *Teva's regulatory submissions and litigation*

[33] The following chart summarizes the steps involved in the approval of Novo-ramipril.

DATE	EVENT
December 24, 2001	Teva files ANDS for Novo-ramipril capsules. The ANDS include Form Vs, stating Teva would await expiry of the '087, '206 and '457 Patents
July 18, 2003	Teva obtains DINs for Novo-ramipril 2.5, 5 and 10 mg capsules
October 14, 2003	Teva is placed on "patent hold"
September 12, 2005	Notice of allegation #1 – '206 Patent
September 14, 2005	Notice of allegation #2 – '089, '948, '549 and '387 Patents
October 31, 2005	Sanofi files a Notice of Application with respect to notice of allegation #1 (Court File No. T-1965-05)
November 2, 2005	Sanofi files a Notice of Application with respect to notice of allegation #2 (Court File No. T-1979-05)
December 13, 2005	'457 Patent expires
September 25, 2006	Federal Court dismisses T-1965-05 "as an abuse of process" (*Sanofi-Aventis Canada Inc v Novopharm Limited* , 2006 FC 1135, 306 FTR 56)
December 8, 2006	The Minister of Health advises that Teva was required to address the '089 and '948 Patents, but not the '549 and '387 Patents

DATE	EVENT
December 15, 2006	Teva withdraws, without prejudice, portionsof notice of allegation #2 relating to the '549 and '387 Patents
April 27, 2007	Federal Court of Appeal dismisses T-1979-05 (notice of allegation #2) as an abuse of process (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167, rev'g 2006 FC 1547)
May 2, 2007	Teva receives an NOC for Novo-ramipril 2.5, 5 and 10 mg capsules

[34] To provide a complete picture, it should be noted that Teva was not the only company challenging the "evergreening patents"; beginning in February 2003 and continuing up to December 2006, Pharmascience, Riva, Apotex, Cobalt Pharmaceuticals Inc. (Cobalt) and Sandoz Canada Inc. (Sandoz) also served notices of allegation. In each and every case, except for Cobalt's August 2006 notice of allegation, Sanofi chose to bring prohibition applications under the *Regulations*.

[35] Following the issuance of Teva's NOC, Sanofi commenced an action against Teva claiming that Teva had infringed the '206 Patent (Court File No. T-1161-07). In a decision dated June 29, 2009, this Court dismissed that action and a companion claim against Apotex in Court File No. T-161-07, and declared the '206 Patent to be invalid (*Sanofi-Aventis Canada Inc v Apotex Inc*, 2009 FC 676, 350 FTR 165). That decision was affirmed by the Court of Appeal (*Sanofi-Aventis Canada Inc v Apotex Inc*, 2011 FCA 300, 426 NR 196). At the time of writing, Sanofi's application for leave to appeal to the Supreme Court of Canada remains pending.

V. Relevant Period

[36] Section 8 allows a second person to claim compensation for the losses it suffered because it was kept off the market during the period of the automatic stay (*Alendronate (FC)*, above at para 97; *Alendronate (FCA)*, above at para 71). A critical determination for the Court is thus the commencement and end dates of the period of liability, defined in these Reasons as the Relevant Period. The parties agree that the end date for the Relevant Period is April 27, 2007. There is no agreement on the appropriate commencement date.

[37] As set out in s. 8(1)(a) of the *PM (NOC) Regulations*, a first person (Sanofi) is liable to a second person (Teva) for any loss suffered during the period:

(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that	*a)* débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :
. . .	. . .
(ii) a date other than the certified date is more appropriate . . .	(ii) soit qu'une date autre que la date attestée est plus appropriée;

[38] In *Alendronate (FC)*, above at paragraphs 106-116, Justice Hughes explained that s. 8 thus gives the Court discretion to select a more appropriate date for the beginning of the liability period, although the presumptive period begins on the patent hold date.

[39] Here, the parties appear to agree that “the date, as certified by the Minister, on which a notice of compliance would have been issued” is October 14, 2003. This date is set out in a letter dated October 17, 2003 from Health Canada to Teva.

[40] In spite of the certification date, each of Sanofi and Teva argues that I should find a different date for the commencement of the Relevant Period. Teva urges me to find a commencement date of July 18, 2003 or, at least no later than August 1, 2003, while Sanofi asserts that the Relevant Period should not begin until December 13, 2005. From the evidence before me, it appears that the following dates should be considered as possible commencement dates:

1. July 18, 2003, when Teva received its DINs for ramipril from Health Canada;

2. October 14, 2003, when Health Canada completed its review of Teva’s drug submission and Teva was advised that an NOC would not issue until the requirements of the *Regulations* were met;

3. October 31, 2005, when Sanofi served and filed a Notice of Application in respect of a notice of allegation served by Teva on September 12, 2005, thereby triggering the statutory stay provided for in s. 7(1)(e) of the *Regulations*; and

4. December 13, 2005, the date of expiry of the '457 Patent, which was the subject of the patent hold referred to in 2 above.

[41] Teva submits that, but for the *Regulations*, an NOC would have been issued to it soon after July 18, 2003, when it received its DINs for Novo-ramipril 2.5, 5 and 10 mg capsules. As of that date, Teva had satisfied all of the clinical and manufacturing requirements set out in the *F&D Regulations*. As adamantly stated by Mr. Windross, upon receipt of the DINs on July 18, 2003, Teva would have been "in a launch mode pending the receipt of the Notice of Compliance". **[Redacted]** Thus, Teva asserts that either July 18, 2003 or – at the latest, August 1, 2003 – must be the beginning date contemplated by s. 8(1)(a) of the *Regulations*. In addition, Teva argues that at the very latest, the damages period should be calculated beginning on the certification date of October 14, 2003. As at any of those dates, in the absence of the *Regulations,* Teva argues that it would have been able to enter the market.

[42] I have no reason to doubt Teva's submissions that it could have physically been prepared to launch Novo-ramipril in the 2.5, 5 and 10 mg strengths on or about August 1, 2003. The question, however, is whether that is the correct date for the assessment of damages under the *PM (NOC) Regulations*. In particular, Teva's arguments must be considered in light of the fact that, as of Teva's patent hold date, Teva had agreed, through its election in its Form V, to await the expiry of the '457 Patent. Moreover, the statutory stay did not begin until October 31, 2005, when Sanofi filed its first of two Notices of Application in response to Teva's notices of allegation.

[43] This case thus presents the somewhat unusual situation in which the certified, or "patent hold" date precedes the beginning of the statutory stay. The first sub-issue related to the commencement date is accordingly whether the Relevant Period can begin prior to the statutory stay.

A. *Can the Relevant Period begin prior to the imposition of the 24-month statutory stay*?

[44] Whether the Relevant Period can begin prior to the imposition of the 24-month statutory stay is a question of statutory interpretation of the relevant provisions of the *Regulations*. Once this determination is made, the question that follows is to determine what would be the appropriate date for the beginning of the period.

[45] Teva's argument for a date prior to both the certification date and the beginning of the statutory stay is premised on its claim that the start date must be determined "in the absence of these *Regulations*". According to Teva, the consequence of these words is "that the second person's losses are to be assessed on the basis it was able to come to market as soon as the health and safety review of its submission had been completed". More specifically, Teva says that it means "the date on which the requirements of the *Food and Drugs Act* were complied with such that the second person would have received its NOC". Teva asserts that factors such as the existence of patents on the Patent Register, Form Vs and the timing of notices of allegation are "irrelevant" in a world where there are no *PM (NOC) Regulations*. Teva submits that, in the absence of the *Regulations*, the Minister would have had a "legal duty" to issue its NOC as of July 18, 2003 (see *Abbott Laboratories Ltd v Canada (Minister of Health*), 2007 FC 622 at

para 11, 57 CPR (4th) 450; *Apotex Inc v Canada (Attorney General)* (1993), [1994] 1 FC 742, [1993] FCJ No 1098 (CA)).

[46] Teva buttresses its contention that all aspects of s. 8 damages must be calculated "in the absence of [the] Regulations" with a number of arguments. In summary form, Teva points out that ss. 8(1)(a), 8(2), and 8(4) all refer to s. 8(1); and that Sanofi commenced proceedings in full knowledge of the fact that Teva had approval in July 2003, and thus knowingly accepted a "black box of liability". Teva also stresses that s. 8 must have a deterrent effect, and alleges that Sanofi's arguments "co-mingle" real events with the "but for" world.

[47] Teva expressly rejects the argument that the liability period cannot begin before the commencement of the statutory stay on the basis that such a position would require an impermissible "radical re-writing and reading in" of the *Regulations*. This, Teva says, is because the legislator clearly chose not to draft s. 8(1)(a) to provide that the liability begins on the later of the certification date or the date of the commencement of a prohibition application. While acknowledging that an application is necessary, Teva maintains that it is "not determinative of the start date".

[48] At its heart, Teva's argument is founded on a misinterpretation of the phrase "in the absence of these Regulations", which inappropriately divorces s. 8 from the rest of the *Regulations*. For the reasons explained below, Teva's arguments must be rejected.

[49] First, Teva's claim that the start date must be determined "in the absence of [the] Regulations" overstates the effect of that phrase in s. 8(1)(a). As stated by the Court of Appeal in *Alendronate (FCA)*, above at paragraph 83,

> The words of section 8 must be read in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme of the *PM(NOC) Regulations*, their object, and the intention of Parliament (*Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559 at paras. 29 and 30, as applied in *Biolyse*, *supra*, at para. 43). Where regulations are concerned, the purpose of the enabling statute must also be considered (*Biolyse*, *supra*, para. 47).

[50] The phrase "in the absence of these Regulations" appears only in s. 8(1)(a), and immediately follows the phrase "on which a notice of compliance would have been issued". Read in their ordinary and grammatical sense, the phrase "in the absence of these Regulations" only modifies the certification date. While Teva points out that ss. 8(2) and (4) both refer to s. 8(1), it is notable that the phrase "in the absence of the Regulations" does not itself appear in any of those subsections. Nor does it appear in s. 8(5), which describes the factors the Court may consider in assessing the amount of a second person's compensation.

[51] The decision in *Norfloxacin (FCA)*, above, also supports limiting the effect of the words "in the absence of these Regulations" to the certification date. In that case, at paragraph 75, the Court of Appeal defined the issue presented by s. 8 as "what would have happened had Merck not brought an application for prohibition" (emphasis added). The Court of Appeal did not define the issue as "what would have happened if the *Regulations* did not exist". The phrase "in the absence of these Regulations" in s. 8(1)(a) therefore logically refers to the absence of the s. 6 prohibition order, not to the absence of the *PM (NOC) Regulations* generally.

[52] If accepted, Teva's interpretation would artificially separate s. 8 from the rest of the *Regulations*. While Teva rightly points out that the *Regulations* do not explicitly state that the liability period begins on the date that a first person commences a prohibition application, this, as Sanofi argues, is the necessary consequence of the fact that s. 8(1) makes a prohibition application a prerequisite for recovery. Subsection 8(1) expressly refers to the statutory stay by predicating a first person's liability upon the withdrawal, discontinuance, or dismissal of a prohibition application "made under subsection 6(1)" (emphasis added), or the reversal of a prohibition order. As described above, s. 6(1) allows a first person who has been served with a notice of allegation to apply to a court for an order prohibiting the Minister from issuing an NOC until after the expiration of the patent that is the subject of the notice of allegation. It is this application by the first person that prevents the Minister from issuing an NOC to a second person (*Regulations*, above at s. 7(1)(e)). Contrary to Teva's suggestion, limiting a first person's liability to some period following the commencement of the statutory stay would therefore not require a "radical re-writing and reading in" of the *Regulations*, as s. 8(1) already references the statutory stay.

[53] This interpretation of s. 8 is consistent with the Court of Appeal's decision in *Alendronate (FCA)*. In determining whether Justice Hughes had erred in holding that he had jurisdiction to hear Apotex's s. 8 claim, the Court of Appeal noted that s. 8 provides a remedy in respect of patents pursuant to s. 20(2) of the *Federal Courts Act*, RSC 1985, c F-7 by "allowing a second person to recover losses arising from the automatic stay triggered by a first person when the attempt to assert its patent rights fail" (*Alendronate (FCA)*, above at para 71[emphasis added]). Similarly, in assessing the constitutionality of s. 8, the Court of Appeal stated, at

paragraph 66 of its decision, that “an award of damages under section 8 logically flows from the section 6 prohibition proceedings”. The period of liability is thus clearly linked to the operation of the automatic stay.

[54] This conclusion is also reinforced by the Regulatory Impact Assessment Statement (RIAS) filed with the introduction of each of the 1993, 1998 and 2006 versions of the *Regulations*. In describing the anticipated impact of the *Regulations*, the 1993 RIAS explained that, although the *Regulations* may unjustifiably delay generics from entering the market (for example, where the patents are later found to be invalid or not infringed), “the frequency and costs associated with any such delays arising from these Regulations will be minimized by the fact that such a patentee will be liable for all damage suffered from the delay” (Regulatory Impact Analysis Statement, (1993) C Gaz II, 1387 at 1388 [1993 RIAS] [emphasis added]). The 1993 RIAS thus clearly links a second person’s damages to the operation of the stay.

[55] A similar statement is found in the 1998 RIAS. That document explains that amendments to the *Regulations* clarified “the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug” (Regulatory Impact Analysis Statement, (1998) C Gaz II, 1055 at 1056 [emphasis added]). The 2006 RIAS also links a first person’s liability to the operation of the stay by explaining that amendments to s. 8 “further specify the matters the court may take into account when calculating the period of delay for which an innovator may be held liable” and “remove the word ‘profits’ from the provision prescribing the remedies available to a generic manufacturer seeking

compensation for any loss arising from that delay" (Regulatory Impact Analysis Statement, (2006) C Gaz II, 1503 at 1521 [2006 RIAS] [emphasis added]).

[56] While Teva points to *Alendronate (FC)* in support of the proposition that the service of an NOA is "entirely irrelevant" to the commencement date, its reliance on that case is misplaced. Specifically, Teva points to paragraph 106, where Justice Hughes observed that "[t]here is nothing to suggest that the Minister knew about or even cared when the Notice of Allegation was served . . .". However, the issue in *Alendronate (FC)* was whether another date was more appropriate under s. 8(1)(a) in light of the fact that Apotex had allegedly delayed serving its notice of allegation for 66 days. Justice Hughes rejected Merck's argument on the basis that there was no evidence to suggest that the date of service of Apotex's notice of allegation impacted the sending of the Minister's patent hold letter (*Alendronate (FC)*, above at paras 112-116). The issue of whether the liability period could begin prior to the statutory stay did not arise in *Alendronate (FC)* because, on the facts before Justice Hughes, the notice of allegation was sent and prohibition proceedings were commenced almost one year before Apotex's patent hold date (see *Alendronate (FC)*, above at para 5). The issue that arises in the case before me is not simply whether the patent hold letter would have been sent on some other date; rather, the question is whether the liability period can begin prior to the statutory stay.

[57] Teva's claim that it is "inequitable" to link causation to the commencement of the stay because "Sanofi benefited from having listed patents on the *Patent Register* for a much more extensive period" is similarly wide of the mark. The very purpose of s. 8 damages is to compensate a second person for "losses arising from the automatic stay" (*Alendronate (FCA)*,

above at para 71). It is irrelevant whether, as Teva alleges, Sanofi would have commenced proceedings against Teva at whatever time Teva sent its notices of allegation.

[58] Even if Teva's interpretation of s. 8 were accepted, ordinary damages principles would prevent a second person from recovering for any loss suffered prior to the beginning of the statutory stay. First, no conduct by Sanofi can be said to have "caused" any damage to Teva during that period. While Teva accuses Sanofi of incorrectly seeking to "narrowly tie causation to its commencement of proceedings under the *Regulations*", Teva does not point to any other conduct by Sanofi that can be said to have caused Teva's alleged losses prior to the commencement of the stay. Teva's only argument appears to be that Sanofi benefited from listing successive patents on the Patent Register. However, Teva does not specifically link that conduct to any of its alleged losses. This is insufficient to establish causation.

[59] Further, Sanofi correctly argues that any loss suffered by a second person prior to the service of a notice of allegation is unforeseeable, because, at that time, the first person has no knowledge of a second person's confidential drug submission. The evidence is clear that ANDS submissions and subsequent actions by Health Canada (such as the issuance of DINs and patent hold letters) are confidential. Ms. Bowes testified that ANDS are not typically disclosed, with the exception of portions disclosed pursuant to orders made under the *Regulations* and product monographs that become public. Prior to the service of the notice of allegation, then, Sanofi had no notice of Teva's intentions. If some conduct by Sanofi had been capable of triggering its liability during this period, then Sanofi would have had no opportunity to alter its actions so as to reduce or avoid liability. The fact that Sanofi knew, from the date it received Teva's first notice

of allegation, that Teva had approval in July 2003, is not enough. It would still be fundamentally unfair to hold Sanofi liable for any loss Teva suffered when Sanofi had no ability to control its liability.

[60] For the foregoing reasons, Teva's interpretation of s. 8(1)(a) and the effect of the words "in the absence of these Regulations" on the commencement date must be rejected. Reading the words of s. 8 in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme of the *PM (NOC) Regulations*, their object, and the intention of Parliament results in a conclusion that the liability period cannot predate the statutory stay.

B. *What is the appropriate commencement date for the Relevant Period*?

[61] Given that I have determined that the Relevant Period cannot begin prior to the date of a statutory stay imposed by the *Regulations*, the question is whether, on the facts of this case, the "more appropriate" date is: (a) October 31, 2005, the commencement of the statutory stay; or (b) December 13, 2005, the date of the expiry of the '457 Patent.

[62] Sanofi argues that December 13, 2005, the date of the expiry of the '457 Patent, is the appropriate commencement date. In support of its position, Sanofi relies on the facts surrounding Teva's choices as to when and how it would approach regulatory approval for its ramipril.

[63] As described above, Teva filed its ANDS for Novo-ramipril on December 24, 2001. In that filing, Teva included an acknowledgement in its Form V that it would await the expiry of the

'087, '206 and '457 Patents before coming to market. According to the Form V filed with the Minister, Teva had no intention of bringing its ramipril product to market until the expiry of several of the related patents. This situation did not change until September 12 and 14, 2005, when Teva filed its notices of allegation for ramipril. Even then, however, Teva did not allege invalidity or non-infringement of the '457 Patent.

[64] I accept that the changing of a Form V is an administrative amendment. It is clear that Teva could have amended its Form V and proceeded to serve a notice of allegation with respect to the '457 Patent. However, it never did so.

[65] I also accept the evidence of Teva's fact witnesses – most notably, Mr. Fishman, Mr. Windross and Dr. Denike – who spoke to the aggressiveness of Teva (then Novopharm) in and around 2003 in acquiring rights to new drugs. In particular, they spoke to the interest of the company in ramipril. Their evidence, however, rings a little hollow when the company indicated clearly on every administrative form (its Form V and its initial notices of allegation) that it would await the expiry of the '457 Patent. Quite simply, Teva failed to take one of the most basic of steps – a notice of allegation with respect to the '457 Patent – in gaining the right to market ramipril.

[66] In my view, the actions of Teva were more consistent with a decision to wait for the expiry of the '457 Patent before launching Novo-ramipril.

[67] By not amending its Form V and by not, at any time, commencing a challenge of the '457 Patent, Teva implicitly agreed to live by the decisions made with respect to other companies (specifically, Apotex and Riva) who did challenge the '457 Patent. Two of those decisions are of particular relevance in this case.

[68] The first decision arose from Apotex's notice of allegation alleging non-infringement of the '457 Patent served in August 2003. In a decision dated October 11, 2005, Justice Simpson determined that Apotex's allegation of non-infringement of the '457 Patent was not justified and issued an Order of Prohibition, prohibiting the Minister of Health from issuing an NOC for ramipril to Apotex until the expiry of the '457 Patent (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1381, 281 FTR 233 [*Apotex*]). Although Apotex commenced an appeal of this decision (Court of Appeal File No. A-494-05), the appeal was subsequently discontinued on October 13, 2006. In sum, on the evidence before me, Apotex was subject to an order of this Court that prohibited the Minister of Health from issuing an NOC to Apotex until December 13, 2005.

[69] On June 9, 2004, Riva served a notice of allegation alleging invalidity of, *inter alia*, the '457 Patent. The NOC proceedings related to Riva's notices of allegation were heard and disposed of in a decision of Justice Harrington dated May 17, 2007 (*Sanofi-Aventis Inc v Laboratoire Riva Inc*, 2007 FC 532, 315 FTR 59 [*Riva*]). This was after the expiry of the '457 Patent. While Justice Harrington dismissed the Application of Sanofi with respect to the '206 Patent, he refused Riva's request to make any determination with respect to the '457 Patent (*Riva*, above at paras 105-106).

[70] In sum, both Apotex and Riva had the determination to address the '457 Patent head on. In the case of Apotex, the result was a prohibition order that prevented Apotex from coming on to the market prior to the expiry of the '457 Patent. Riva's challenge was wrapped up with the '206 Patent and was not decided prior to the expiry of the '457 Patent.

[71] Another way of looking at this situation is to consider the behaviour of Teva in a hypothetical scenario that would exist in the total absence of the *PM (NOC) Regulations*. In that "but for" world, patents would exist. The rights and obligations associated with those existing patents would be governed by the *Patent Act*, RSC 1985, c P-4 [*Patent Act*]. The patents are presumed to be valid. In the face of an existing patent, a third party seeking to use the patent may do a number of things; five that come to mind are as follows:

1. it may use the patented subject matter and await the consequences of an infringement action;

2. it may negotiate a licence agreement with the patentee;

3. it may commence an impeachment proceeding;

4. it may wait for the expiry of the patents; or

5. it may wait for another third party to succeed in impeaching the relevant patent.

[72] While the evidence shows that Teva was aggressively attempting to bring new products to market in 2003, I have no evidence that Teva would have launched ramipril in the face of a valid '457 Patent. There is no evidence that Teva had obtained a legal opinion on the validity of the '457 Patent. We know that Teva never attempted to negotiate a licence agreement; nor did it commence any impeachment proceedings on the '457 Patent. It seems to me that the facts demonstrate that, given the '457 Patent was set to expire in the not-too-distant future, on December 13, 2005, it is more likely than not that Teva was prepared to wait and to enter the market when the '457 Patent expired. Alternatively, Teva was waiting for another party to successfully challenge the '457 Patent. In either case, Teva would not have come on to the market until December 13, 2005.

[73] Dr. Denike, who testified on behalf of Teva, was intimately involved with all aspects of Teva's litigation strategy in 2002 when the company was examining its ability to launch ramipril. The following exchange is highly telling of Teva's strategy with respect to patent litigation:

> THE WITNESS: . . . We do know once another generic started in litigation, the practice that I had while I was there and after I left was, seeing somebody else was already litigating, I might as well sit and learn what was happening there and react to what was happening, because they are going to allow the other generics to go forward anyway. So if there was a problem in the first generic litigation, I could take a different strategy, because I believe I was going to be released at the same time, there was no point in starting right away. I might as well sit back and get the free information that's there and deal with it.
>
> JUSTICE SNIDER: On the basis of that assumption, you would not be first, you'd just be one of?
>
> THE WITNESS: One of. First or tied for first.

> JUSTICE SNIDER: And that was good enough?
>
> THE WITNESS: Tied for first -- first was always the golden chalice. But tied for first was clearly the expectation and always the number one target. If you can't be first, make sure you're tied.
>
> JUSTICE SNIDER: So by sitting back, Novopharm was admitting, in a hypothetical because you weren't there at the time, but in general, based on your experience when you were there, by sitting back you were agreeing, well, can't be first, we're going to be tied?
>
> THE WITNESS: Tied for first.
>
> [Emphasis added]

[74] Teva offered many excuses for initially indicating that it would await the expiry of the '457 Patent on its Form V. However, at the end of the day, Teva made a business decision. There are consequences to business decisions. Teva voluntarily sat on the sidelines while others actively – and unsuccessfully – sought to gain market entry in the face of the '457 Patent. While Teva could have amended its Form V, it did not do so. While Teva could have challenged the '457 Patent through the *PM (NOC) Regulations* or through an impeachment action, it did not do so.

[75] Accordingly, I conclude that the appropriate commencement date, for the purposes of s. 8 of the *Regulations*, is the date of the expiry of the '457 Patent – December 13, 2005.

[76] Indeed, even if I had found that the *Regulations* permit the period of liability to commence prior to the imposition of the statutory stay, I would still conclude that, on the evidence before me, the appropriate date for the beginning of the Relevant Period is December 13, 2005.

VI. Overall Size of the Ramipril Market

[77] Having determined the Relevant Period of December 13, 2005 to April 27, 2007, the next step is to assess the size of the total ramipril market during this hypothetical period. Stated in different terms, I must estimate the total number of capsules of ramipril that would have been sold by all manufacturers during the Relevant Period. This figure represents the Ramipril Market. In this task, I was assisted by two economists, Dr. Anis (produced by Teva) and Dr. Carbone (produced by Sanofi). Each of these experts prepared estimates of the size of the Ramipril Market, using very different modeling techniques. In addition, I had the evidence of Dr. Cockburn whose mandate was, as I see it, to do no more or less than to criticize Dr. Anis's expert opinion. Dr. Cockburn made no estimate of his own.

[78] Each of Dr. Anis and Dr. Carbone was asked to provide opinions on the size of the overall Ramipril Market in a number of scenarios. Each expert addressed one scenario that closely matches the Relevant Period of December 13, 2005 to April 27, 2007. Specifically:

- Dr. Anis defines his Scenario 5(ii) as "Teva Canada entered together with Apotex and another generic" for the period "December 2005 to May 2, 2007" (Exhibit 47 at para 65).

- Dr. Carbone defines his Scenario 5 as simultaneous entry into the generic market by Teva, Apotex and an AG on December 13, 2005, prior to entry by PMS and

Riva (Exhibit 86, vol 1 at paras 128-129). Dr. Carbone calculates the size of the anticipated market until April 27, 2007.

[79] I note that Dr. Anis's definition of Scenario 5(ii) differs from the "but for" world defined in these Reasons in two ways. First, Dr. Anis's evaluation period appears to be slightly longer than the Relevant Period. Second, Dr. Anis appears to indicate that the third generic (other than Teva and Apotex) is not an AG (I discuss competition in the Generic Market in Part VIII. C, below). In spite of these two variances, it appears that this scenario most closely aligns with the "but for" world that I find in these Reasons and is, therefore, the best available comparison to Dr. Carbone's results.

[80] The experts arrived at different estimates of the size of the total Ramipril Market in the "but for" world. These differences resulted from their divergent conclusions regarding the effect of a cessation of promotion by Sanofi upon the entry of generic manufacturers into the ramipril market (also referred to as the "genericization" of the market). Both Dr. Anis and Dr. Carbone conducted their analyses on the basis that Sanofi would have ceased its advertising efforts upon the genericization of ramipril (Exhibit 47 at para 113; Exhibit 86, vol 1 at paras 67-70). I would accept this as a reasonable assumption.

[81] In his analysis, Dr. Anis assumes that the cessation of advertising would <u>not</u> have had a significant impact on the size of the Ramipril Market. Dr. Anis thus concludes that the total quantity of Ramipril sold in the "but for" world would have been equal to the actual quantity of Ramipril sold during the Relevant Period (Exhibit 47, Schedule "K" at 11). Dr. Anis therefore

uses actual monthly sales data for all ramipril products sold during the Relevant Period to calculate the Ramipril Market size.

[82] To test his assumption, Dr. Anis performs a "sensitivity analysis" by constructing two regression models (Models S1 and S2) to estimate the effect of advertising on the size of the Ramipril Market. From these models, Dr. Anis concludes that ceasing promotion is not a statistically significant determinant of Ramipril Market size (Exhibit 47, Schedule "K" at 12).

[83] In contrast, Dr. Carbone assumes that the Ramipril Market would be influenced by Sanofi's advertising behaviour. In support of his opinion, Dr. Carbone points out that the actual ramipril market did in fact shrink upon genericization (Exhibit 86, vol 1 at para 68).

[84] Based on his assumption that a decline in advertising is significant, Dr. Carbone employs a time-series forecasting method to estimate the impact of generic entry on the size of the Ramipril Market. This method involves four phases:

- Phase One: Dr. Carbone uses market data for the period prior to the actual formulary listing of generic ramipril to forecast the size of the ramipril market after the formulary listing date, assuming that no generics entered the market.

- Phase Two: Dr. Carbone subtracts the forecasted sales of ramipril after the formulary listing date (i.e. the quantity forecasted in Phase One) from actual sales of ramipril after the formulary listing date. He then divides this difference by the

forecasted sales. His calculation produces a series of “impact percentages” which represent the impact of generic competition on the size of the ramipril market (see Exhibit 86, vol 1 at Table 7). Dr. Carbone observes that generic competition reduced the size of the ramipril market over time for all formulations except the 1.25 mg strength (Exhibit 86, vol 1 at para 66).

- Phase Three: Dr. Carbone constructs an “impact model” using a process called Bass Diffusion modelling. This technique estimates the change in ramipril sales over time based on the manner in which demand reacts to influences on product diffusion such as advertising, media coverage and word of mouth by customers already using the product (the Impact Model) (Exhibit 86, vol 1 at Appendix “J”). The purpose of the Impact Model is to predict the (negative) linear trend in ramipril market size based on the impact percentages calculated in Phase Two.

- Phase Four: Dr. Carbone subtracts the values generated by the Impact Model from the size of the ramipril market (without generic competition) forecasted in Phase One. The result is the total forecasted size of the Ramipril Market over the Relevant Period.

[85] It is important to note that, although Drs. Anis and Carbone were generally characterized as using contrasting “econometric” and “time-series forecasting” models, that distinction does not apply to this aspect of their analyses. That is because Dr. Anis does not use an econometric model to predict the size of the Ramipril Market. Instead, he assumes that ceasing promotion

would not affect the overall size of the market, and uses his model to test that assumption. The "time-series forecasting" and "econometric" methods used by the experts therefore do not conflict at this stage of the analysis. The question that I must instead answer is whether, based on the evidence before me, it is reasonable to assume that Sanofi's decision to stop promoting ALTACE upon genericization would impact market demand for the drug.

[86] Dr. Carbone criticized Dr. Anis's conclusion that generic entry would have no impact on the size of the Ramipril Market. He argued that Dr. Anis's econometric model is of no statistical value because it does not include enough observations (data points) to render accurate predictions. In support of his argument, Dr. Carbone pointed out that Dr. Anis's model failed to predict the known impact of the HOPE study on ramipril sales (Exhibit 87 at para 44).

[87] Dr. Cockburn was also critical of Dr. Anis's conclusion on this point. In particular, he criticized Dr. Anis for not including factors such as the availability of alternative treatments in his model, and reiterated Dr. Carbone's concern that Dr. Anis's dataset is not sufficiently large to produce reliable estimates. In addition, Dr. Cockburn noted that Dr. Anis does not account for the persistent effect of advertising over time, and fails to explain how he constructs an average price for competing products (Exhibit 158 at paras 59-62).

[88] In response, Dr. Anis offered the pragmatic observation that the differences in the Ramipril Market size estimated by himself and Dr. Carbone are "minimal and not significant" (Exhibit 48 at para 19). Dr. Anis quantifies these differences for Dr. Carbone's Scenario 5 in Table 2 of his Responding Report (reproduced below) and provides a visual representation of

these differences in Figures 2.1 to 2.18. The percent difference between Dr. Anis's and Dr. Carbone's predicted Ramipril Market size for all years ranges from 0.58% to 3.2%, depending on the formulation, although these differences are higher in some years:

Table 2. Comparison of total ramipril market based on Carbone Scenario 5

Strength	YEAR	Anis IMS CDH EU	Carbone Ex-factory	Percent: Anis/Carbone	Percent Difference*
2.5MG	2005 (Dec)	5,828,610	6,228,461	93.60%	-6.60%
	2006	67,361,500	71,647,787	94.00%	-6.20%
	2007 (Jan-Apr)	24,605,630	23,099,000	106.50%	6.30%
	Total	**97,795,740**	**100,975,248**	**96.85%**	**-3.20%**
5MG	2005 (Dec)	10,861,350	11,732,696	92.60%	-7.70%
	2006	126,245,990	132,748,325	95.10%	-5.00%
	2007 (Jan-Apr)	45,898,420	43,696,315	105.00%	4.90%
	Total	**183,005,760**	**188,177,336**	**97.25%**	**-2.79%**
10MG	2005 (Dec)	18,628,400	20,003,022	93.10%	-7.10%
	2006	223,164,400	227,084,419	98.30%	-1.70%
	2007 (Jan-Apr)	78,306,430	74,882,010	104.60%	4.50%
	Total	**320,099,230**	**321,969,451**	**99.42%**	**-0.58%**

Percent difference is calculated as 100(Anis IMS CDH EU-Carbone ex-factory)/average (Anis IMS CDH EU, Carbone ex-factory)

[89] While these differences may be relatively small, I find that the criticisms of Dr. Anis's approach are valid and call into question the explanatory power of his econometric Models S1 and S2. All else being equal, the reliability of an econometric model increases with the number of observations included in the data set. Models that test a hypothesis or assumption on the basis of a small number of observations are statistically less reliable than those estimated using a large number of observations. From a methodological standpoint, Dr. Anis's models simply do not appear to contain enough information on which to make a reliable finding that ceasing or decreasing advertising would not affect the size of the Ramipril Market in the "but for" world.

[90] I also accept Dr. Carbone's observation that actual demand for ramipril did, in fact, decline after generic entry. To the extent that this observation is accurate, it supports Dr. Carbone's conclusion that Sanofi's decision to cease advertising would have also led to a decrease in the size of the Ramipril Market in the "but for" world.

[91] I am unable to draw any specific conclusions about the comparative validity of Dr. Carbone's time-series forecasting approach to predict the size of the Ramipril Market. Dr. Anis does not offer any specific criticisms of this approach at this stage of the analysis. I can only conclude that Dr. Carbone's approach appears to provide one means to account for the effect of genericization on the size of Ramipril Market, assuming that such an effect would have occurred in the "but for" world and can be estimated using available data from the observed ramipril sales. For this reason, I am prepared to accept, as reasonable, Dr. Carbone's estimate under his Scenario 5 as the size of the Ramipril Market during the Relevant Period.

[92] The following table presents the total number of ramipril capsules (10, 5 and 2.5 mg formulations) calculated using Dr. Carbone's predictions for his Scenario 5 (Exhibit 88 at Supplemental Appendix S). This number represents the size of the total Ramipril Market:

Total Number of Pills, Carbone Scenario 5

	December 2005 - April 2007
Total Ramipril Market Size	611,122,083

VII. Size of the Generic Market

[93] Having determined the size of the overall Ramipril Market during the Relevant Period, the next step is to establish the size of the Generic Market. This requires that I calculate the percentage of the Ramipril Market that generic entrants would have captured. The notion that generic manufacturers would have acquired a portion of the Ramipril Market is described as "market penetration" or, from the innovator's perspective, "market erosion". In either case, the issue is to determine how ALTACE and generic versions of ramipril would have shared the Ramipril Market.

[94] Once again, I turn to the economists, Dr. Anis and Dr. Carbone, for assistance. Again, I focus on Dr. Anis's Scenario 5(ii) and Dr. Carbone's Scenario 5, both of which approximate the Relevant Period.

[95] At this stage of the analysis, the experts took quite different approaches. Dr. Anis assumed that the erosion curve for ALTACE could be approximated by the average erosion curve of drugs that enjoyed sales in the top 25% of all drug markets. In contrast, Dr. Carbone estimated ALTACE's erosion curve using a time-series forecasting model. Again, I do not find that the difference between the experts turns on the distinction between econometric and time-series forecasting models, as Dr. Anis did not employ an econometric model for his analysis. I must accordingly find some other basis for determining which approach, if any, is of assistance in determining the size of the Generic Market.

[96] Dr. Carbone directed a number of criticisms at Dr. Anis's method of constructing and selecting the appropriate erosion curve. These include:

1. Dr. Anis has improperly calculated his average quartile erosion curves using post-genericization dollar sales (Exhibit 87 at paras 27-28);

2. erosion curves for individual provinces should have been estimated separately given provinces' different formulary listing dates and observed differences in erosion rates for cardiovascular products between provinces (Exhibit 87 at para 18);

3. erosion curves based on the Canadian Drug Store and Hospital Purchases (CDH) audit data will tend to over-state the erosion rate at the beginning of the period after generic entry because it does not account for accumulated inventory after the formulary listing date (Exhibit 87 at para 21);

4. Dr. Anis's approach lacks transparency because it is impossible to link his average erosion curves to the underlying data. Dr. Anis does not present specific erosion rates (only the graphical curves) and his choice of the Q4 average erosion curve appears to be based only on a subjective visual evaluation;

5. Dr. Anis's method fails to control for additional factors that may impact on the erosion rate of ALTACE; and

6. the Q4 erosion curve is not a "conservative estimate" of ALTACE's erosion rate, as Dr. Anis claims – particularly for Quebec, where the observed ALTACE curve is above the average Q4 curve for the first 24 months after initial generic entry.

[97] In oral testimony, Dr. Anis clarified that Dr. Carbone's first criticism is based on a misunderstanding of his method. Dr. Anis explained that:

> We looked at the sales of each one of the molecules in my sample and, according to the magnitude of the sales, companies or manufacturers got into different quartiles, depending on the size of the thing; this is the pre-genericization sales. And subsequently, the erosion curves were made on physical units; it has nothing to do with dollars or adding sales volumes.

[98] The third criticism involves Dr. Anis's use of CDH data. By way of background, both experts prepared their reports using data provided by IMS, an independent firm that collects and provides audited drug consumption data. Two of those audits are the Canadian CompuScript audit and the CDH audit. Dr. Anis explained that the CompuScript audit tracks the number of prescriptions dispensed by Canadian retail pharmacies. In contrast, the CDH audit provides the dollar value and unit volume of pharmaceutical and diagnostic products purchased by Canadian retail pharmacies and hospitals. Dr. Anis testified that transactions will appear in the CDH database as soon as the drug is shipped to the wholesaler or pharmacist; they will not appear in the CompuScript database until a prescription is dispensed.

[99] In response to Dr. Carbone's criticism, Dr. Anis argues that the CDH dataset is appropriate because "the erosion process should be considered to have started as soon as the generic product is available" and not adjusted for the "inventory" factor. He argues that the

relevant transaction for the purposes of calculating damages in this proceeding is between Teva and the supplier. Apart from this issue, Dr. Anis does not offer any further criticism of Dr. Carbone's time-series forecasting method for predicting the Generic Market size.

[100] With respect to the fifth criticism, Dr. Anis testified that he did not expect matters such as therapeutic class, type of product, or provincial regulations to impact on his calculation of the average erosion rate.

[101] Because, as Dr. Carbone points out, Dr. Anis has failed to provide actual erosion rates for his calculated average Q4 erosion curve, it is not possible to quantify the extent to which the experts' methods yield different predictions of the size of the Generic Market. Without this kind of quantitative comparison, it is difficult to draw any reliable conclusions as to the significance of Dr. Carbone's remaining criticisms.

[102] In light of Dr. Anis's clarifications, there do not appear to be any significant flaws in his method of calculating average quartile erosion curves. However, I observe that Dr. Anis has failed to provide a rigorous explanation to justify his choice of the Q4 curve. Dr. Anis puts forward the hypothesis that drugs with relatively large sales volumes prior to generic entry would attract greater generic interest and competition because they are potentially more profitable. Therefore, he expects branded drug sales to erode "faster" and "deeper" the larger the size of the market before generic entry (Exhibit 47 at paras 82, 88). Presumably, Dr. Anis could have constructed an econometric model to test this hypothesis using an approach similar to the one he

employed in estimating the size of the Ramipril Market. No such model was provided, nor did Dr. Anis offer an explanation for this choice.

[103] Regrettably, I am unable to draw any specific conclusions as to the validity of Dr. Carbone's time-series forecasting approach aside from the fact that accepting Dr. Anis's claim that CDH data is more appropriate would mean that Dr. Carbone's predictions may underestimate the size of the Generic Market. The only observation that I can make is that Dr. Carbone's use of a forecasting approach is conceptually consistent with his methodology in estimating the size of the Ramipril Market, whereas Dr. Anis apparently chose to rely on different methodologies at each of these stages.

[104] Marginally, I therefore prefer the analysis and, hence, the results obtained by Dr. Carbone with respect to the size of the Generic Market.

[105] The following table presents Dr. Carbone's estimates for both the Ramipril Market and the Generic Market (Exhibit 88 at Supplemental Appendix S):

Total Number of Pills, Carbone Scenario 5

	December 2005 - April 2007
Total Ramipril Market Size	611,122,083
Total Generic Market Size	374,092,845

[106] Having made this determination, I can move on to the two remaining issues – Teva's share of the Generic Market (i.e. Teva's Lost Volumes) and the calculation of Teva's losses during the Relevant Period (i.e. Teva's Net Lost Profits).

VIII. Teva's Lost Volumes

[107] The next step in the analysis is for me to determine Teva's share of the Generic Market.

[108] I begin by observing that Sanofi does not argue that Teva would have been unable to produce sufficient quantities of ramipril to supply whatever market share it would have acquired in the "but for" world. The evidence before me is clear and compelling that Teva would have had the means to obtain sufficient quantities of API and incipient ingredients and sufficient plant capacity to meet market demand throughout the Relevant Period.

[109] Having found that Teva could have supplied the entire market, the question is whether Teva would have captured the entire Generic Market. Before I can quantify Teva's share of the generic market, preliminary questions regarding the composition of the Generic Market must be resolved.

[110] Teva submits that, as a matter of law and principle, it should be considered to be the only generic manufacturer of ramipril during the Relevant Period. Even if I decide that other generics could have entered the market, Teva urges me to ignore the hypothetical actions of other generics during the Relevant Period.

[111] Sanofi, on the other hand, asserts that the "but for" world should include other generic manufacturers. Indeed, Sanofi's position is that there can only be one "but for" world that must apply to all potential s. 8 litigants. On the facts of this case, Sanofi suggests that it is likely that

both Apotex and an authorized generic would have entered the market simultaneously with Teva on December 13, 2005.

[112] I will consider each party's arguments in turn, as they each raise distinct sub-issues. I will then proceed to determine the volume of ramipril capsules that Teva would have sold on the basis of any competition in the "but for" world.

A. *Should the assessment be made on the basis that Teva would be the sole generic in the "but for" world*?

[113] Teva advances several arguments in support of its position that s. 8 does not require consideration of the actions of third party generics. In summary form, Teva's arguments are that s. 8 should reflect the exclusive dispute between a first and second person under s. 6; Sanofi's liability would be unfairly limited if other generics were included in the analysis; and considering the actions of third parties would allow Sanofi to "cherry-pick evidence". For the reasons set out below, I find that Teva's arguments are unpersuasive. Teva's damages must be assessed in light of any competition that would have existed in the Generic Market.

[114] With respect to its first argument, Teva submits that the *Regulations* are a complete code, and that s. 8 arises out of an exclusive dispute between a first and second person. It follows, in Teva's view, that a second person's losses should be quantified on this same "exclusive" basis, and that it is "not fair or reasonable to look at all generics under section 8 … when section 6 restricts the universe to the first and the second person". Teva also argues that "it would be manifestly unworkable to approach this otherwise", noting that multiple scenarios would have to

be modeled and that extensive document discovery would be required. The task of recreating a single hypothetical market is so complex, Teva says, that Parliament would have had to expressly provide for that result had it been intended.

[115] In this argument, Teva conflates the cause of action with the remedy. In particular, Teva's position overstates the effect of s. 6, which describes a first person's right to apply for a prohibition order. Section 6 does not define the factors that the Court may consider in assessing any damages to which a second person may become entitled under s. 8.

[116] Teva's interpretation of s. 8 also ignores the clear words of s. 8(5), which requires that a court assessing a second person's compensation "take into account all matters that it considers relevant to the assessment of the amount" (emphasis added). Competition in the generic market is clearly relevant to a second person's recovery. While the *Regulations* are, as Teva argues, a "complete code" (*Apotex Inc v Syntex Pharmaceuticals International Ltd*, 2005 FCA 424, [2006] 3 FCR 318 and *Merck Frosst Canada Inc v Apotex Inc*, [1997] 2 FC 561, [1997] FCJ No 149 (CA)), the Court of Appeal has held that s. 8(5) gives the Court a "broad discretion" to consider a number of factors in assessing the amount of a second person's compensation (*Apotex Inc v Merck & Co*, 2011 FCA 364 at paras 37-38, [2011] FCJ No 1865). Consideration of the market share that would have been captured by competitors is relevant to a s. 8 claim, much as it is to any damages claim. This follows from general damages principles, which seek to place a successful plaintiff in the position he or she would have occupied but for the defendant's wrong.

[117] Although, as Teva suggests, the s. 8 calculation would be somewhat simpler if the Court ignored other generics, the fundamental question would remain the same; Teva would still be required to prove its lost sales. More importantly, "[p]rocedural simplicity and economy" are not ends in themselves. These principles do not appear in s. 8, and, in any event, cannot usurp the Court's obligation to arrive at an assessment of the amount of compensation equivalent to the loss Teva suffered during the liability period. As the Court of Appeal noted in *Alendronate (FCA)*, above at paragraph 89, "[t]he compensation provided is for prejudice actually suffered by a second person by reason of the operation of the stay". Sanofi is correct in pointing out that s. 8 damages must be consistent with both reality and the principle that s. 8 damages are compensatory in nature.

[118] While Teva is similarly correct in stating that each case must be decided on its own facts, that principle is not inconsistent with consideration of other generic manufacturers. The findings a court makes as to the market share each generic would have captured in the hypothetical world must be made on the facts of each case, and will depend on the evidence each party is able to marshal. Considering the conduct of other generics does not require that the Court import findings made in one proceeding into subsequent actions.

[119] Teva's second argument – that Sanofi's liability would be "capped inappropriately" if the Court considered other generic competitors – is also unpersuasive. The heart of this argument appears to be the fact that Sanofi's total s. 8 liability is less than its profits. Including other generics in the s. 8 analysis, Teva says, would further reduce each generic's damages, as they

"would be left fighting over damages that cumulatively amount to substantially less than the profits Sanofi actually made".

[120] While Teva's argument may have some appeal from a policy perspective, it fundamentally misconceives the nature of s. 8 damages. Subsection 8(1) makes a first person liable to a second person for "any loss suffered during the [liability] period". There is no requirement that Sanofi's total liability resemble the profits it earned on the sale of ALTACE during the period of the stay. Moreover, it is settled law that s. 8 does not entitle a second person to disgorgement of a first person's profits (*Alendronate (FCA)*, above at paras 89-91; *Apotex Inc v Eli Lilly Canada Inc*, 2011 FCA 358 at para 23, 426 NR 173). Teva's argument attempts to obtain a form of disgorgement by another means, and must be rejected.

[121] Finally, Teva argues that the Court should refuse to consider Sanofi's contention that other generics would have entered the market during the liability period because "[h]aving abused the *Regulations*, evergreened its monopoly and obstructed and delayed Teva's market entry, Sanofi ought not to be permitted to cherry-pick evidence from non-parties, and create its own ideal 'but for' world to try to reduce Teva's section 8 damages". This concern is addressed by the ordinary rules of evidence and the standard of proof.

[122] In finding that s. 8 requires consideration of generic competition in the hypothetical world, I note that this approach is consistent with the decision of the UK courts in *Les Laboratoires Servier and another v Apotex Inc and others*, [2008] EWHC 2347 (Ch) (QL), [2008] All ER (D) 79 (Oct), rev'd on other grounds [2010] EWCA Civ 279, [2010] All ER (D)

238 (Nov) [*Servier*]. That case arose out of Servier's patent for perindopril, and concerned the enforcement of a cross undertaking in damages. Servier had obtained an interim injunction restraining Apotex from selling perindopril until trial, while permitting it to fulfill existing binding orders. Servier's patent was subsequently found to be invalid, and the injunction was discharged. This decision concerned the quantification of Apotex's losses. In setting out the applicable legal principles, the court noted at paragraph 5(e) that "[t]he profits that Apotex would have made from its exploitation of the opportunity to sell generic perindopril depend in part upon the hypothetical actions of third parties (other potential market participants) and in part upon Servier's response to them".

[123] In assessing Teva's share of the Generic Market, I will accordingly consider the market share that other generics would have captured in the "but for" world.

B. *Should the assessment be made on the basis that there is only one "but for" world*?

[124] Sanofi not only argues against Teva's "sole generic" interpretation of the *Regulations*, but further asserts that there can be only one "but for" world that should apply to all s. 8 claims for ramipril. In Sanofi's view, a second person would receive an inappropriate windfall if all other generics were not considered. Sanofi explains that, absent a single finding as to the overall generic market in the "but for" world, damages would have "no relationship to the multi-generic market that actually exists", and "would be proportional to the number of players in the market". Sanofi elaborates on this last point by explaining that "[i]f there [were] 10 generic entrants into the marketplace you could have 10 parties asserting a claim they would have been the sole

generic". Sanofi submits that considering each generic as a sole source manufacturer is contrary to common sense, and would create a situation in which generics "would be better off litigating under the regulations than actually selling their drug in the competitive marketplace". This, Sanofi says, would run contrary to the purpose of the Regulations, which it believes "are supposed to encourage generic competition". Finally, Sanofi argues that such an interpretation would be "completely inconsistent with reality and completely inconsistent with the compensatory nature of section 8".

[125] While I agree with Sanofi that the "but for" world must consider the presence of potential competitors, I do not go so far as Sanofi asserts. In other words, I reject Sanofi's urging that I establish one "but for" world that will apply in this case and in any others involving the genericization of ramipril.

[126] The assessment of damages can and should be made on the facts of each case. To the extent that there are common elements that impact on the quantification of damages, these will more likely than not come forth during the trial.

[127] A serious flaw in Sanofi's argument is that the evidence in one case may establish a different Relevant Period than in another case. This will impact on many elements of the assessment of damages. In this case, for example, I have determined that Teva would have entered the market on December 13, 2005. This finding means that different considerations will come into play with respect to the possible entry of an authorized generic than if I had concluded that a different entry date was more appropriate. In the companion Apotex case (Court File No.

T-1357-09), I have concluded that a different Relevant Period is applicable; different considerations flow from that finding. Accepting Sanofi's position would, accordingly, require that I disregard evidence in either Apotex's case or this one. Such a result is unsupportable.

[128] I agree with Sanofi that the *PM (NOC) Regulations* contemplate a "multi-generic" universe. However, where I disagree with Sanofi is that the Court must develop one "universe" that accommodates each and every possible s. 8 case. By their very nature, s. 8 damages are hypothetical. It follows that estimates must be made and a market constructed that will not be perfect. As pointed out by Lord Shaw in *Watson, Laidlaw & Co Ld v Pott, Cassels, and Williamson* (1914), 31 RPC 104 at 118 (HL):

> The restoration by way of compensation is therefore accomplished to a large extent by the exercise of a sound imagination and the practice of the broad axe.

[129] With respect to ramipril, Sanofi has identified only Teva, Apotex and Riva as participants in the "but for" world. I am quite certain that the damages of those three actions will not be greatly – if at all – in excess of the award of damages that would be made had the three cases been joined and one "but for" world established. Since Sanofi is the defendant in all three cases, it is well aware of the total damages being claimed. If that amount raised a real possibility that Sanofi's total liability would exceed the bounds of rationality, Sanofi could urge the Court to consider an adjustment pursuant to s. 8(5).

[130] There may be a situation where Sanofi's fear has some merit. It certainly is not this case.

C. *What other generics would have entered the market*?

[131] Having determined that other generics should be considered in the "but for" world, the next task is to establish which generics would have entered the market during the Relevant Period and when they would have entered. Before I examine the individual market entrants, I note some disagreement as to the burden.

(1) Burden

[132] Teva submits that it bears the burden of establishing its losses, but that this only requires demonstrating that it had the capacity to supply the entire market at the relevant time. Teva argues that it is not required to "prove the negative", or "that no one else would have taken its sales". According to Teva, "the burden is resoundingly on Sanofi to disprove Teva's entitlement to all of its losses". In particular, Teva says that Sanofi bears the burden of establishing what actions Riva, Pharmascience and Apotex would have taken in the "but for" world. Teva explains that Sanofi should have to prove precise entry dates, capacity, API supply, uninterrupted production, willingness to tolerate an at risk launch, competitive impact, and that each generic went to market with the approved formulation – in other words, "the same things … that Teva has had the burden of proving in order to establish its claim for damages and losses".

[133] Teva cites *Norfloxacin (FCA)* as authority for the proposition that a claimant bears the burden of proving what would have likely happened in the but for world, but argues that it cannot be Teva's burden to "call … every potential participant in the market and prove that they

wouldn't have launched". Teva also draws an analogy to the burden in an accounting of profits, explaining that Teva would have to prove that it was likely to make its claimed sales, while Sanofi would have to prove that there is a reason to reduce them.

[134] In addition, Teva argues that, "[h]aving taken the advantage of the automatic prohibitions, it is only fitting that Sanofi should bear the burden of convincingly demonstrating any exculpatory factors it wants the Court to consider".

[135] Sanofi rejects Teva's claim that Sanofi bears the burden of proving that there would have been other generics in the market, arguing instead that Teva must prove that it would have been the sole generic, and that it would have made the claimed sales. Further, Sanofi cites *Eli Lilly and Co v Apotex Inc*, 2009 FC 991 at paras 762, 771-841, 859, aff'd 2010 FCA 240, 409 NR 173, leave to appeal to SCC refused, [2010] SCCA No 434, for the proposition that a plaintiff "has the burden of establishing that it did suffer damages, not simply that it 'could' have suffered damages".

[136] It is trite law that there are both legal and evidential burdens in a trial. In *Hoffmann-La Roche Ltd v Canada (Minister of National Health and Welfare)* (1996), 205 NR 331 at para 8(3) (CA), 70 CPR (3d) 206, the Court of Appeal explained that:

> [The primary] burden, known in a civil case as either the "persuasive burden" or the "legal burden", is the burden of establishing a case to the civil standard of proof. By contrast, the "evidential burden" consists of the burden of putting an issue in play and means that a party has the responsibility to ensure that there is sufficient evidence of the existence or nonexistence of a fact or an issue on the record to pass the threshold for that particular fact or issue.

[137] The legal burden does not shift over the course of a trial, but the evidential burden does. Once there is "*prima facie* proof or presumption of the truth of an allegation, which ought therefore to be found true in the absence of further evidence", the evidential burden shifts to a defendant "to adduce evidence in answer to the *prima facie* proof" (*Ontario Equitable Life and Accident Insurance Co v Baker*, [1926] SCR 297 at 308-309 [*Baker*]). At the end of a case, the court must weigh all of the evidence called by both parties (*Baker*, above).

[138] It cannot be Teva's burden to call every potential participant in the market and prove that they would not have launched. In this regard, the position of Teva is much like the situation faced by the defendant in *Rainbow Industrial Caterers Ltd v Canadian National Railway Co.*, [1991] 3 SCR 3, [1991] SCJ No 67. In that case, involving an action in tort, Rainbow was seeking damages from Canadian National Railway (CN) for, *inter alia*, negligent misrepresentation in respect of a catering contract. CN argued that the claimed loss was not all attributable to CN since Rainbow would have entered into other contracts. On the issue of burden, at page 15, the Supreme Court states that:

> Once the loss occasioned by the transaction is established, the plaintiff has discharged the burden of proof with respect to damages. A defendant who alleges that a plaintiff would have entered into a transaction on different terms sets up a new issue. It is an issue that requires the court to speculate as to what would have happened in a hypothetical situation. It is an area in which it is usually impossible to adduce concrete evidence. In the absence of evidence to support a finding on this issue, should the plaintiff or defendant bear the risk of non-persuasion? Must the plaintiff negate all speculative hypotheses about his position if the

> defendant had not committed a tort or must the tortfeasor who sets up this hypothetical situation establish it?
>
> [Emphasis added]

[139] In holding that CN bore the burden, the Supreme Court commented as follows, at page 16:

> The appellant CN alleged that the loss was not all attributable to the misrepresentation because Rainbow would have entered into a different contract on other terms which would have resulted in at least some of the loss. What the respondent would have done had it not been for the tortious act requires a great deal of speculation, and, on the basis of the principles which I have reviewed above, I would apply the legal burden of proof against the appellant.

[140] In the context of an undertaking in damages, a successful defendant bears the onus of proving its loss (see e.g. *Servier*, above at para 9). However, in *Algonquin Mercantile Corp v Dart Industries Canada Ltd* (1987), [1988] 2 FC 305 (QL) at para 8 (CA), [1987] FCJ No 540), the Federal Court of Appeal held that an unsuccessful plaintiff bears the burden of proving cannibalization where that issue was raised by the plaintiff:

> [T]he existence of cannibalization was a question which was introduced into the debate as a result of plaintiff's allegations. Accordingly, it was for plaintiff to prove it, not for defendant to show, as the Trial Judge said, that it "would not have occurred".

[141] Taking all of this into consideration, in my view, the proper approach is the following: Once Teva has led *prima facie* evidence of its losses, the evidential burden shifts to Sanofi to adduce evidence in response. Sanofi cannot simply allege that other generics would have entered the market without leading evidence in support of such assertions.

[142] In this case, Teva does not, at least initially, bear the burden of disproving the hypothetical sales of third party generics. However, Teva, at all times, bears the legal burden of proving its losses, and the evidence adduced by Teva must ultimately be weighed against any evidence adduced by Sanofi establishing sales by third party generics. To the extent that Sanofi succeeds in discharging its evidential burden by proving third party sales, Teva must address that evidence in order to discharge its legal burden.

(2) Apotex

[143] Sanofi submits that Apotex would have been a participant in the hypothetical world during the entire Relevant Period. Specifically, it seems to be Sanofi's preferred position that Apotex would have commenced sales of ramipril on December 13, 2005, a date that coincides with the date of entry of Teva. Teva submits that Sanofi has entirely failed to meet its burden of proving that Apotex was in a position to enter the market and would have done so.

[144] There are two aspects to the question of whether Apotex would have commenced sales in the hypothetical world. The first step is to examine the regulatory context to determine whether there were regulatory impediments to Apotex's entry. The analysis of this question will lead to a determination of the possible date for Apotex's launch of a generic version of ramipril. As a second step, I must address the practical considerations that would have likely arisen as of the hypothetical entry date. Such matters as plant capacity, access to API and motivation are relevant at this second step.

[145] In the hypothetical world that I am creating for the purposes of determining Teva's claim, from a regulatory and practical perspective, would Apotex have been able to come to market and, if so, when?

[146] We know that, in the real world, Apotex submitted its ANDS for approval of Apo-ramipril on July 31, 2003. As summarized in Exhibit 143, the subsequent steps involved in obtaining approval to sell Apo-ramipril were as follows:

DATE	**EVENT**
July 31, 2003	Apotex filed ANDS for Apo-ramipril capsules
June 20, 2003	NOA #1 – '206 Patent; postmarked August 5, 2003
September 23, 2003	T-1742-03 (NOA #1) commenced
August 20, 2003	NOA #2 – '457 Patent – non-infringement
October 8, 2003	T-1851-03 (NOA #2) commenced
November 10, 2003	NOA #3 – '457 Patent – validity
November 17, 2003	NOA #4 – '089 Patent
December 29, 2003	T-2459-03 (NOA #3) commenced
January 5, 2004	T-11-04 (NOA #4) commenced
April 6, 2004	Apotex's "patent hold"
June 28, 2004	NOA #5 – '948 Patent
August 16, 2004	T-1499-04 (NOA #5) commenced
September 20, 2005	Federal Court dismisses T-1742-03 (NOA #1)
October 6, 2005	Federal Court issues a prohibition Order until the expiry of the '457 Patent in T-1851-03 (NOA #2)
October 27, 2005	Federal Court dismisses T-11-04 (NOA #4)
November 4, 2005	Federal Court dismisses T-2459-03 (NOA #3)
November 29, 2005	NOA #6 – '549 and '387 Patents

DATE	EVENT
December 13, 2005	'457 Patent expires
January 17, 2006	T-87-06 (NOA #6) commenced
June 27, 2006	Federal Court dismisses T-1499-04 (NOA #5)
December 8, 2006	Minister advises that Apotex was not required to address the '549 and '387 Patents
December 12, 2006	Apotex receives NOC
May 2, 2008	Federal Court dismisses T-87-06 (NOA #6) “as moot”

[147] Apotex received its “patent hold” letter on April 26, 2004 (Exhibit 142, Tab 7). That is, as of April 26, 2004, Apotex was advised that the examination of its ANDS was complete, but that an NOC would not issue until the requirements of the *Regulations* had been met. Ultimately, Apotex received approval to sell four strengths of ramipril on December 12, 2006.

[148] There was one very serious constraint on Apotex’s participation in any market – real or hypothetical. This was the Prohibition Order dated October 6, 2005, prohibiting the Minister from issuing an NOC to Apotex until the expiry of the '457 Patent on December 13, 2005. The Order arose from the decision of Justice Simpson in *Apotex,* above, in which she concluded that Apotex’s allegations of non-infringement in its Notice of Allegation #2 were not justified. Although Apotex commenced an appeal of this decision (see Court of Appeal File No. A-494-05; Exhibit 142, Tab 18), the appeal was subsequently discontinued on October 13, 2006 (Exhibit 142, Tab 19). On the basis of the Prohibition Order, Apotex could not have come to market with Apo-ramipril any earlier than December 13, 2005, that being the date of expiry of the '457 Patent.

[149] As of December 13, 2005, three other NOC proceedings commenced by Sanofi had already been dismissed:

- Notice of Application #1, with respect to the '206 Patent, had been dismissed by a decision of this Court dated September 20, 2005 in Court File No. T-1742-03 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283, 278 FTR 1);

- Notice of Application #4, with respect to the '089 Patent, had been dismissed by a decision of this Court dated October 27, 2005 in Court File No. T-11-04 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461, 283 FTR 1); and

- Notice of Application #3, with respect to the validity of the '457 Patent, had been dismissed by a decision of this Court dated November 4, 2005 in Court File No. T-2459-03 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1504, 283 FTR 171).

[150] There could obviously have been some interplay between the Court's dismissal of Notice of Application #3 and the Prohibition Order. Both addressed the '457 Patent. Perhaps, there was a way in which Apotex could have challenged the Prohibition Order. In this trial, however, neither Sanofi nor Teva argues that the Prohibition Order would have been without effect or unenforceable as of November 4, 2005. Accordingly, on the record and arguments before me, I will assume that the Prohibition Order remained in place as an impediment to Apotex's market entry until December 13, 2005.

[151] As of December 13, 2005, two notices of allegation remained outstanding with respect to the '948 Patent (#5) and the '549 and '387 Patents (#6). The subject matter of the '948 Patent was ramipril together with a calcium antagonist for the treatment of proteinuria. This is not an indication for which Apotex ever sought approval. Similarly, the '549 and '387 Patents were for the use of ramipril for what has been called the “HOPE indications”, discussed in greater detail in Part IX.G, below. In the real world, Apotex was permitted to obtain its NOC when it removed the HOPE indications from its product monograph. Neither Sanofi nor Teva argues that the outstanding Notices of Application would have prevented Apotex from coming to market on December 13, 2005.

[152] Teva points to two alleged problems in the evidence of Apotex’s approvability. First, Teva states that there is no evidence of any letter from the Minister of Health certifying that, in the absence of the *Regulations*, Apotex would have received its NOC in April of 2004. Absent such evidence, Teva argues, there is no basis to assume that the letter from Health Canada to Apotex dated April 29, 2004 advising Apotex of its April 26, 2004 patent hold date (Exhibit 142, Tab 7) was not superseded by a later letter. In my view, there is no need for Sanofi to “prove” that Apotex received a letter of certification. I am not attempting to establish a commencement date for Apotex’s s. 8 damages claim. Rather, I am examining a hypothetical situation. A certification letter regarding Apo-ramipril would have been helpful and relevant, but it is not the only evidence that can assist me. As is widely understood, an NOC will issue following the approval of an ANDS. Moreover, Teva could have asked Apotex’s chairman and chief executive officer, Dr. Sherman, or Ms. Bowes whether the letter of April 29, 2004 had been superseded. On the basis of the record before me, I accept the “patent hold” letter from Health Canada to

Apotex dated April 29, 2004 as sufficient evidence to establish Apotex's approvability as of December 13, 2005.

[153] Teva's second assertion is that there is no evidence that the formulation actually sold by Apotex is the formulation that was approvable in April of 2004. Apotex's approved product monograph (dated December 12, 2006) bears two submissions numbers, #85886 and #91920. Teva points out that this means that there are two submissions which relate to that product monograph and that no evidence was led to explain this additional submission (#91920), including whether it relates to a different formulation. Thus, according to Teva, Sanofi has failed to establish that Apotex is even selling Apo-ramipril pursuant to the submission that was approved in April 2004 (#85886). This argument, in my view, unhelpfully mixes the real world with the hypothetical scenario that I am trying to build. I am satisfied that, in the "but for" world, Apotex would have been able to bring Apo-ramipril to market based on the April 2004 approval. The question as to which formulation was actually brought to market in late 2006 is simply irrelevant.

[154] For these reasons and based on the record before me, I conclude that Apotex would likely have had the necessary regulatory approvals to bring Apo-ramipril to market as of December 13, 2005. I turn now to the practical issues.

[155] On the practical side, it is necessary to address two questions: Would Apotex have been able to obtain sufficient quantities of ramipril API; and would Apotex have had adequate plant capacity to supply the Generic Market (or at least its share of the hypothetical market)?

[156] Teva submits that Sanofi has failed to establish the following:

- Sanofi led no evidence identifying Apotex's API supplier or its ability to supply.

- Sanofi has not proved that Apotex had the capacity to manufacture Apo-ramipril capsules.

- It is not clear that, if faced with being alone in the market, in an "at risk" situation, Apotex would have launched ramipril aggressively or at all.

[157] Dr. Sherman was subpoenaed by Sanofi to testify in this trial. On the basis of his evidence, I am persuaded that it is more likely than not that Apotex would have been able to acquire sufficient API to meet its needs in the "but for" world. Ramipril API, as discussed by Dr. Sherman, would have been available in the Relevant Period. There was no need for Sanofi to identify any particular supplier of Apotex's API since this is a hypothetical analysis. Based on the evidence of many witnesses, including a representative from the API supplier, **[Redacted]**, who was put forward by Teva, I am satisfied that API would have been as easily obtained by Apotex as it would have been by Teva. Moreover, logically, if Teva, as it insists, could have acquired enough API to supply the entire market, there must have been sufficient API available to Apotex to supply a part of that market. Finally, no one has pointed to any problems with the supply of ramipril API following the actual entry of generics into the market.

[158] With respect to plant capacity, Dr. Sherman was presented with a chart showing annual production at Apotex's solid dosage plants (Exhibit 142, Tab 8). This chart demonstrates that Apotex would have had ample capacity to produce large volumes of Apo-ramipril over the Relevant Period.

[159] The final point made by Teva relates to Apotex's likely behaviour in the face of an "at-risk" launch. That term is commonly used to refer to the situation in which a generic manufacturer succeeds in obtaining an NOC under the *Regulations*, but faces the possibility of being sued for patent infringement upon the launch of its product. Dr. Sherman admitted that Apotex assesses patent risk and takes steps to minimize its exposure in "at risk" situations, for example through seeking higher prices for product (e.g. perindopril), agreements with brand companies (e.g. atorvastatin) and development of non-infringing processes and formulations (e.g. esomeprazole). Teva submits that there is a lack of convincing evidence to suggest that Apotex would not have taken such precautions in the case of ramipril.

[160] I do not accept this "spin" on Dr. Sherman's evidence. Teva put forward no evidence of its own to question the credibility of Dr. Sherman. Indeed, Dr. Sherman, who was very credible on this point, described the aggressiveness of Apotex in taking litigation risks. When asked whether Apotex was the first Canadian company to develop a "first-and-alone" strategy, Dr. Sherman provided the following response:

> I think all generic companies essentially have the same strategy. We have certainly grown because we have been the best at it in many cases where we came to market well ahead of competitors who for various reasons didn't see certain opportunities, and the reverse has happened too.

[161] The very fact that Apotex was prepared to commence multiple attacks on the validity of any and all of Sanofi's patents on ramipril, while Teva stood by for years, speaks volumes to Apotex's willingness to assume risk. Between June 2003 and November 2005, Apotex served six notices of allegation covering every one of the ramipril patents. In addition, I am not even certain that Apotex's hypothetical launch on December 13, 2005 would have been an at-risk launch. As discussed above, by that date, Apotex would likely have cleared all of the regulatory impediments to its launch of Apo-ramipril.

[162] I am satisfied that, throughout the Relevant Period, Apotex would have been able to obtain ramipril API and had the plant capacity to manufacture sufficient quantities of Apo-ramipril to supply its hypothetical share of the market. In addition, Apotex would have likely met its regulatory requirements and chosen to launch its product.

[163] Overall, the evidence supports a conclusion that Apotex would have been a market participant during the entire Relevant Period.

(3) Riva

[164] Several possible scenarios were discussed during the trial that involved the participation of Riva in the "but for" world. As with the possible participation of Apotex in the hypothetical market, there are two aspects to Riva's possible entry during the Relevant Period. The first step is to examine the regulatory context to determine whether there were regulatory impediments to Riva's entry. The second step is to address the practical considerations that would have likely

arisen as of the hypothetical entry date. Such matters as plant capacity, access to API and motivation are relevant at this second step.

[165] The problem is that the evidence before me establishes that Riva could not have received an NOC for its ramipril during the Relevant Period. Thus, even if Riva could have made arrangements to market ramipril in some or all parts of Canada, it could not have come to market in the Relevant Period due to a regulatory or legal impediment.

[166] On June 8, 2004, Riva submitted its ANDS to Health Canada for ramipril capsules in the 2.5, 5 and 10 mg strengths (Exhibit 115, Tab 74).

[167] On June 21, 2004, Health Canada advised Riva that its examination of the submission was completed and that the NOC would not issue until the requirements of the *PM (NOC) Regulations* were met. At the time, although they were not listed in the letter, those requirements included addressing the listed patents. A further – and ultimately more problematic – issue for Riva arose from its submission to cross-reference the submission of Pharmascience for pms-ramipril. In Riva's case, the company submitted a cross-referenced ANDS which was substantially identical to Pharmascience's original submissions (Exhibit 115, Tab 74). Riva's submission also included a copy of Pharmascience's letter providing access to its data in support of Riva's application. In addition, Riva requested that new DINs be assigned for its products (Exhibit 115, Tab 74).

[168] As confirmed by Ms. Bowes, Health Canada' policy and its advice to Riva was that it could not get an NOC for ramipril in advance of Pharmascience obtaining its NOC. Riva was informed of this regulatory hurdle in a letter from Health Canada dated April 24, 2007 (Exhibit 115, Tab 66) in which Riva was advised as follows:

> [W]e would note that, since Riva's submission has been cross-referenced with another submission, the NOC will not be issued to Riva until the NOC is issued for the cross-referenced submission for pms-ramipril, in accordance with Health Canada's Policy entitled "Filing of Supplemental New Drug Submissions, Supplemental Abbreviated New Drug Submissions, Notifiable Changes and Cross-Referenced Submissions".

[169] On May 24, 2007, Riva brought an application for judicial review of Heath Canada's refusal (Exhibit 115, Tab 67; Court File No. T-896-07). Health Canada subsequently reversed its position and, in a letter dated June 21, 2007 (Exhibit 115, Tab 69), Riva was informed as follows:

> Health Canada is no longer of the view that Riva cannot receive a notice of compliance until such time as the Pharmascience submission to which Riva's product is 'cross-referenced' is itself approved. As a result, should Riva ultimately be successful in the prohibition proceedings ongoing in T-127-07, and otherwise meet all of its obligations under the *Patented Medicines (Notice of Compliance) Regulations*, it will be eligible to receive a notice of compliance, regardless of whether the Pharmascience submission has fully complied with the *NOC Regulations* and received a notice of compliance.

[170] The application for judicial review was discontinued. However, the fact is that, separate and apart from any notice of allegation proceedings under the *Regulations*, Riva could not have entered the ramipril market before Health Canada changed its position on Riva's cross-referenced ANDS. The earliest that Riva could have obtained an NOC is June 21, 2007,

after the end date of the Relevant Period in this trial. Neither Sanofi nor Teva presented evidence or argument that Riva could have entered the market during the Relevant Period.

[171] Given the facts before me in this case, I conclude that Riva would not have been a participant in the generic "but for" world during the Relevant Period.

(4) Authorized generic

[172] There was disagreement between the parties as to whether and when an authorized generic version of ramipril would have been introduced in the "but for" world.

[173] As described by a number of witnesses, the term "authorized generic", or "AG", refers to a drug that is manufactured by an innovative drug company – in this case, Sanofi – but sold by a generic company under the generic's name. While the composition of the authorized generic product is identical to the innovator's product, it has a separate DIN. Authorized generics obtain regulatory approval by submitting an administrative NDS instead of an ANDS. No bioequivalence study is required, as the authorized generic product is manufactured by the innovator. As a result, it is faster for authorized generics to obtain approval. Ms. Friedman explained that authorized generic agreements allow innovators to participate in both the brand and generic markets, as the innovator effectively sells two distinct, but identical products.

[174] In a genericized market, the introduction of an AG permits the brand company to recoup some of the market that has been lost to generics. It is obvious that a brand company will not

introduce a generic until and unless there is an unauthorized or “true” generic manufacturer coming on to the market. Otherwise, the AG would only cannibalize sales of the brand drug.

[175] When ramipril was finally genericized in late 2006, the first market entrant was ratiopharm operating as an AG of Sanofi. Anticipating a generic entrant, Sanofi had entered into an agreement with ratiopharm allowing it to rely on Sanofi’s regulatory filings to obtain an NOC ahead of the pack. Would Sanofi have undertaken the same actions in the “but for” world and launched an authorized generic during the Relevant Period? Teva argues that it would not have done so and Sanofi submits that it would have. There are three sub-issues to be addressed: (a) should the Court consider an AG in the analysis of the generic market in the “but for” world; (b) would Sanofi have launched an AG; and (c) could Sanofi have been in a position to launch an AG as of December 13, 2005?

(a) *The inclusion of an AG in the “but for” world*

[176] Teva argues, as its first position, that the Court should not consider an AG in the analysis of its compensation because:

1. Such arguments are self-serving and in most cases will lack an evidentiary foundation.

2. The fact that Sanofi "aggressively listed patents" and "pursued applications in the Federal Court despite having no chance of success" makes it inequitable to reduce Teva's damages on the basis of an AG.

3. It would reduce Teva's damages.

4. The AG argument is "repugnant to the underlying purpose and intent of the regulations".

[177] Sanofi's main response to these arguments appears to be that the evidence demonstrates that Sanofi's claim is not self-serving because Sanofi genuinely contemplated an AG as a means of mitigating its losses. Sanofi thus appears to acknowledge that there is a potential for an AG argument to be used as a "shield of liability".

[178] As discussed below, the evidence in this case indicates that it is more likely than not that Sanofi would have launched an AG in the "but for" world. Teva's first argument is, therefore, inapplicable on the facts of this case, although it could be relevant in a future case. That is particularly so in light of Dr. Sherman's testimony regarding what he describes as the anti-competitive nature of AGs. In particular, Dr. Sherman testified that AGs are unfair for at least two reasons. First, AGs allow innovators to reduce a generic's potential profits (and s. 8 damages) and thus dissuade generics from investing in certain products. Second, an AG's low price is subsidized by the sales an innovator continues to make at a high price, as well as the tax subsidy innovators receive by recording the loss they suffer from selling an AG below cost

against income earned from the higher priced sales of the innovator's own product. Dr. Sherman also testified that AGs are subsidized because they do not have to engage in litigation or research and development, and do not face any risk of liability for infringement from the innovator. In a future case where the evidence is different, such considerations might be relevant to an analysis under s. 8(5) of the *Regulations*. I admit to sharing some of the concerns expressed by Dr. Sherman. In this case, however, the evidence establishes that Sanofi would in fact have launched an AG in the "but for" world. Moreover, there is no legal impediment to Sanofi so doing.

[179] Teva's second point, that it would be inequitable to reduce its damages on the basis of an AG because Sanofi "aggressively listed patents" and "pursued applications in the Federal Court despite having no chance of success", is irrelevant. This is because there is no apparent connection between Sanofi's ability to argue that it would have launched an AG and its alleged conduct in other proceedings. Teva inappropriately characterizes the ability to make an AG argument as a privilege.

[180] Teva's third and fourth points can be considered together. It is unarguably the case that the inclusion of an AG in the "but for" world results in a lower award of damages to the second person. However, I am not persuaded that s. 8 precludes the consideration of an AG in assessing the second person's losses.

[181] As pointed out by Sanofi, the *Regulations*, as a whole, contemplate the existence of AGs. Pursuant to s. 7(3), a generic manufacturer can obtain an NOC with the consent of the first person. An AG is a manufacturer entering with the consent of the first person.

[182] Generic drug companies have raised the allegation of inequities caused by AGs in the past. The 2006 RIAS, above at 1525, contains the following remarks:

> As a final note, certain generic drug companies also argued very forcefully that the Government should incorporate measures in these amendments to address what they perceive as diminishing market incentives in their industry. More specifically, they contend that innovators are increasingly entering into licencing arrangements with willing generic companies (so-called "authorized generics") in order to pre-empt genuine generic competitors and retain market share past patent expiry. This practice, which is also said to be prevalent in the US, is currently being studied by the US Federal Trade Commission. While the Government is of the view that there is insufficient information on the impact of this practice on market dynamics in the industry to support regulatory action at this time, it will be examining this practice more closely in response to these concerns.
>
> [Emphasis added]

At that time, the Governor in Council was aware that there was an issue surrounding AGs and chose not to make amendments to exclude consideration of AGs in a claim under s. 8. In the absence of clear statutory language, I cannot simply, as urged by Teva, exclude the AG from the s. 8 assessment.

[183] Section 8 damages compensate a second person for losses it suffered as a result of the automatic stay (*Alendronate (FCA)*, above at para 71). In other words, I am being asked to assess damages as though no prohibition application had been brought (*Norfloxacin (FCA)*, above at

para 75). Excluding an AG where the evidence demonstrates that an AG would have been present would artificially increase Teva's compensation under s. 8. This is because, in such a situation, not only would Teva have been able to launch, but there also would have been no impediment to the launch of an AG by Sanofi. It follows that, by excluding the AG from the "but for" world, Teva's damages would exceed the revenues it would have earned had Sanofi not brought a prohibition application.

[184] In brief, I share the concerns expressed by Teva. Nevertheless, I can see no legitimate means to exclude the existence of an AG (where demonstrable on the facts) from the "but for" market. The Governor in Council would have to make that decision.

(b) *Decision to launch an AG*

[185] The next question is whether it is more likely than not that Sanofi would have decided to launch an authorized generic in the "but for" world.

[186] There are a number of factors that lead me to conclude that Sanofi would have decided to launch an AG to coincide with the hypothetical launch of Teva and Apotex in December 2005, the beginning of the Relevant Period.

[187] Mr. Gravel provided very credible testimony about Sanofi's approach to AGs. He acknowledged that Sanofi does not launch AGs for all of its products upon genericization, and

explained that Sanofi considers a number of factors before deciding whether to launch an authorized generic. **[Redacted]**

[188] One of the most important factors in determining whether Sanofi would have decided to launch an AG is the importance of ALTACE to Sanofi. Mr. Gravel testified that, following the publication of the HOPE study, ALTACE sales "increased significantly year-over-year and became the leading product in Canada". He also stated that at one point, ALTACE was Sanofi's largest product.

[189] A second factor weighing in favour of an AG launch in 2005 is the real world action of Sanofi in authorizing ratiopharm to market ramipril in 2006.

[190] Teva points to a number of instances of "large molecules" where Sanofi did not launch an AG. However, Mr. Gravel explained that, in situations where Sanofi already has a non-generic partner, as it does with Bristol-Myers Squibb in the case of PLAVIX, it must consider that it will be sharing profits with both the AG manufacturers and its partner. On cross-examination, Mr. Gravel acknowledged that Sanofi did not launch an AG upon the genericization of a numbers of its products but maintained that such decisions were made because an AG would not have been profitable for Sanofi. With respect to PLAVIX, Ms. Decelles agreed that even in the context of extremely large drugs, there can be barriers or business considerations that lead Sanofi to forego the loss mitigation it could gain from an AG. **[Redacted]** Sanofi's failure to introduce an AG for a drug it sold in a partnership arrangement does not lead me to conclude that Sanofi would have made the same decision with respect to ALTACE.

[191] Teva's argument that AGs accounted for only a small part of Sanofi's business and accounted for profits of less than $10 million in 2004 is largely irrelevant. What matters is whether Sanofi would have launched an AG for ramipril.

[192] The evidence clearly establishes that Sanofi had contemplated the possibility of generic entry and the launch of an AG for ramipril since at least 1999, due to the fact that the '087 Patent was set to expire in May 2002. Mr. Leprince testified that Sanofi considered the same options in response to the expiry of the '087 Patent as it considered with respect to many patents, and that the "usual process" involved allowing a company called Altimed to market an AG two or three months prior to patent expiry. In that regard, Mr. Leprince spoke to a document which contemplated generic entry in mid-2002. While the document Mr. Leprince spoke to did not actually model the introduction of an AG, it is clear that Sanofi considered that possibility.

[193] Although the issuance of the '206 Patent in 2001 averted the threat of generic entry for a time, Mr. Leprince testified that that threat resurfaced in 2003, when Pharmascience filed a notice of allegation, followed quickly by Apotex. Sanofi also points out that Dr. Sherman's patent application for a ramipril formulation came to Sanofi's attention on April 16, 2003. This application would have raised the threat of an attack on ALTACE by Apotex (Exhibit 97, Tab 59).

[194] Mr. Gravel similarly testified that Sanofi was considering the possibility of generic entry into the ramipril market when he became involved with ALTACE at the end of 1999 and beginning of 2000.

[195] On the basis of this evidence, I am persuaded that it is more likely than not that Sanofi would have determined that it would launch an AG during the Relevant Period to respond to the generic entry by Apotex and Teva.

(c) *Timing of AG launch*

[196] The next question is whether Sanofi would have been prepared to launch an AG to coincide with the entry of Teva and Apotex on December 13, 2005. When would Sanofi have realized that generic entry was imminent? Would Sanofi have been able to find a partner in the "but for" world? Would Sanofi and the AG partner have been able to make the necessary arrangements in time to launch on December 13, 2005?

[197] With respect to Sanofi's knowledge of the imminent market entry of Teva or Apotex, there are a number of factors at play. Sanofi would have known that the Prohibition Order preventing Apotex from coming to market would expire on December 13, 2005. Moreover, on September 20, 2005 and October 27, 2005, the Federal Court dismissed two notices of application brought by Sanofi against Apotex's notices of allegation. The only remaining impediments to Apotex's entry were related to three use patents; Sanofi must have known of the weakness of its reliance on those patents. Sanofi also knew about Dr. Sherman's patent application. Sanofi would have had a clear period of about three months in which to initiate the launch of an AG on December 13, 2005.

[198] Teva submits that ratiopharm would not have likely agreed to launch an AG with Sanofi. The first problem with Teva's argument is that it relates to genericization in 2003; the situation may have been much different in and around the fall of 2005. The evidence demonstrates that Sanofi likely would have been able to find an AG partner between September and December 2005 – if not ratiopharm, then another generic manufacturer. The evidence of Dr. Denike and others was to the effect that there would have been substantial interest in partnering with Sanofi for a ramipril AG. Mr. Gravel testified that Sanofi was also contacted by **[Redacted]** and **[Redacted]** with respect to ramipril in 2005. Ms. Decelles stated that **[Redacted]** and **[Redacted]** contacted her in 2006 regarding an AG agreement for ramipril. Sanofi also considered **[Redacted]** as a potential AG partner. Moreover, Mr. Gravel pointed out that generics would have been interested because ramipril would have been the largest product to be genericized. While Mr. Gravel acknowledged that generics are "not all equal in terms of which one would be the best partner for [Sanofi]" **[Redacted]**, it is more likely than not that Sanofi would have found an acceptable partner in either **[Redacted]**, as the latter company was also listed as a feasible partner in one of Sanofi's analyses. In addition, Ms. Decelles testified that Sanofi also considered partnering with **[Redacted]**.

[199] The final question is whether the arrangements could have been in place to allow a launch of the AG in December 2005. In my view, it is more likely than not that Sanofi could have launched an AG to coincide with the launch of unauthorized generics by Teva and Apotex on December 13, 2005. The company would have had approximately three months, beginning from the dismissal of its first Notice of Application on September 20, 2005, to prepare for

Apotex and Teva's December 13th launch. The evidence demonstrates that Sanofi likely could have been able to prepare an AG for launch within that time frame.

[200] Teva correctly points out that the negotiation of Sanofi's real-world AG agreement with ratiopharm required **[Redacted]**. Sanofi and ratiopharm appear to have first discussed the possibility of an AG sometime in **[Redacted]**, and at least by **[Redacted]**. An agreement in principal was reached in **[Redacted]**, and a letter of intent signed in **[Redacted]**. The final agreement was not concluded until **[Redacted]**.

[201] However, Sanofi persuasively argues that the process could have been expedited in several ways. Both Mr. Gravel and Ms. Decelles testified that Sanofi's lengthy negotiations with ratiopharm reflected the fact that there was no time pressure in the real world. Ms. Decelles testified that the negotiations could have been expedited by **[Redacted]**, thus permitting Sanofi to proceed with some of the operational elements, such as the cross-reference.

[202] With the motivation of generic entry looming in two to three months, it is more likely than not that Sanofi would have done everything possible to complete an agreement with a generic manufacturer for generic launch as of December 13, 2005.

[203] I am also satisfied that Sanofi would have been able to obtain regulatory approval in time to meet the December 13, 2005 launch date. Ms. Mancino testified that, since 2001, the regulatory requirement for an AG has essentially been an administrative submission which includes a copy of administrative forms such as an HBP 30-11 form, the product monograph, a

copy of the package labels, a letter of authorization from the innovator authorizing the generic to cross-reference the innovator's files in support of its application, as well as a letter of consent for the making, constructing and selling of the innovative product.

[204] In addition, Ms. Mancino testified that, although the administrative submission may involve a review of up to 45 days by Health Canada, she has found that such submissions normally only require 30 days. Mr. Woloschuk similarly testified that on average, the issuance of a cross-licence NOC takes 30 days. Moreover, Ms. Decelles testified that, in the actual world, **[Redacted]**.

[205] There are some additional steps to production – such as labelling and preparation of the product. Any such steps could be undertaken quickly. **[Redacted]**

[206] In order to launch an AG, Teva asserts that Sanofi may have also been required to proceed through the company's internal process for approving financial investments, or "AIF" process, **[Redacted]**. **[Redacted]**. It is not clear whether the AIF process would have applied if Sanofi had commenced the negotiation of an AG agreement in September or October of 2005. However, even if an AIF process had been required, common sense tells me that offshore approval for Sanofi's most important and profitable drug would have been almost immediate.

[207] **[Redacted]**, other evidence before me demonstrates that Sanofi could have launched an AG in less time in an urgent situation. The arrangements to enter the market with an AG would,

in my view, have been longer than the **[Redacted]** days asserted by Sanofi but likely within the three month window that I believe Sanofi would have had.

[208] In conclusion on this point, I am satisfied that it is more probable than not that Sanofi would have decided to launch an AG, would have found a partner and would have been able to launch an AG version of ramipril on or about December 13, 2005.

D. *Teva's Lost Volumes*

[209] For the reasons set out above, I have concluded that it is likely that the Generic Market during the Relevant Period would have consisted of Teva, Apotex and an AG, all of which would have entered the market on December 13, 2005. My next task is to determine how these three competitors would have shared the Generic Market. To assist, I turn to the economists who provided opinions on this issue – Drs. Carbone and Anis.

[210] There were significant differences in the determinations made by Drs. Carbone and Anis, and much criticism of each by the parties. However, many of the differences with respect to the sharing of the generic market are minor when one considers the appropriate scenario. As discussed at paragraphs 78 to 79 above, the most relevant scenarios for comparison are Dr. Anis's Scenario 5(ii) and Dr. Carbone's Scenario 5. I will proceed to consider each expert's analysis of the appropriate scenario.

[211] Dr. Anis's approach is to construct an econometric model that incorporates explanatory factors in order to estimate Teva's market share. Although his report does not make his methodology explicit, Dr. Anis appears to rely on his Model 3 to perform this task in Scenario 5(ii). Dr. Anis constructs his Model 3 using data from actual markets with three simultaneous entrants, limited to periods before the entry of a fourth generic. Dr. Anis further restricts his Model 3 dataset to markets where both Apotex and Teva were among the first entrants. These specifications result in a dataset that includes six formulations of three molecules (Exhibit 47, Schedule "K" at 7).

[212] Dr. Anis uses his Model 3 to predict the market share of generic manufacturers in markets with three first movers (called the "independent variable"). Dr. Anis reports that he uses two types of "explanatory variables" in this model: (1) the identity of each generic manufacturer; and (2) whether each generic manufacturer was an AG or not. An explanatory variable contains data that is assumed to explain some portion of the variation in the independent variable across observations. In other words, Dr. Anis seeks to explain why one might observe differences in the market share of generic manufacturers in different markets based on the identity of the generic manufacturer and whether or not a generic manufacturer was an AG. For example, some generic manufacturers might have a competitive advantage over other generic manufacturers and therefore tend to capture a greater share of the market. Dr. Anis's model is designed to test this type of hypothesis and to help identify the direction and magnitude of any statistically significant effects.

[213] Dr. Anis's Model 3 predicts that, when there are three simultaneous entrants in the generic market for a given molecule and formulation, the market share of Teva will on average be 33%, or roughly one-third. As explained by Dr. Anis,

> The finding of relevance from **Model 3** was that in those instances where Teva Canada competed in markets where 3 generics (Teva Canada, Apotex plus another generic) entered the market at the same time and when there were 3 generics competing, on average, Teva Canada had [generic market] share of 33%.
>
> (Exhibit 47 at para 96 [emphasis in original])

[214] Dr. Carbone does not construct a model to estimate Teva's share of the Generic Market. Instead, he applies an "even proportional rule" to determine "the allocation between multiple generic manufacturers entering the same market at the same time" (Exhibit 86, vol 1 at para 99). Dr. Carbone thus assumes an even allocation of market share in the case of simultaneous entry. His main reason for allocating the Generic Market equally is that he is not able to access data about rebates and discounts that could, at the end of the day, have significant impacts on a particular generic's ability to compete. While his approach, in general, appears to be quite arbitrary, the facts in this trial support his conclusion.

[215] In the hypothetical Generic Market that I have found to be likely, Dr. Carbone's "even proportional" assumption produces a generic market share for Teva of 33.3%, roughly equal to Dr. Anis's estimate of 33%. Drs. Anis and Carbone thus generate roughly the same predictions regarding Teva's relative share of the Generic Market. As a result, there appears to be no issue in dispute between these two experts.

[216] There was considerable testimony before me about the ability of an AG to compete in the Generic Market. However, that evidence was anecdotal and incomplete. With respect to Teva and Apotex, there is nothing before me that would lead me to conclude that, with simultaneous entry, either would have a competitive advantage over the other.

[217] In the face of the opinions of Drs. Carbone and Anis, I am prepared to conclude that, in the "but for" world, Teva, Apotex and the AG would have shared the Generic Market equally. In other words, I accept the results of Dr. Carbone's analysis.

[218] In order to calculate Teva's Lost Volumes, I must make the appropriate inventory adjustment. Mr. Hamilton explained this issue in the following terms (Exhibit 163, Schedule 5.4 at fn 3):

> I understand that the forecast information included in the [Carbone Report] has been developed based on IMS EUTRx data, which reflects the Teva prescriptions filled by pharmacists as opposed to Teva sales made to wholesalers and pharmacists. My analysis of Teva's lost profits is based on Teva's lost sales and therefore, an adjustment to the forecast data was required to account for the time lag between Teva making a sale and a pharmacist filling a prescription with Teva-Ramipril capsules. I estimated that this time lag is on average approximately 2 months based on review of Teva's actual sales of Teva-Ramipril subsequent to launch compared to IMS data for the same period of time. Accordingly, my adjustment includes an additional 2 months of capsule sales, which I have assumed to be the first 2 months following the end of the Delay Period ending April 27, 2007 as forecasted in the [Carbone Report].

[219] Applying Mr. Hamilton's inventory adjustment to Dr. Carbone's estimate of Teva's market share, I find that Teva would have sold 147,092,478 capsules during the Relevant Period.

[220] I observe that the number used for Teva's lost sales in Schedule 5.1 of the Final Schedules to the Hamilton Reports is 147,092,476 (Exhibit 163, Tab 5 at 1)), which differs from my calculation by two pills. It appears that the source of this difference is that some of the monthly totals used by Mr. Hamilton in his report differ by a few pills from Dr. Carbone's estimates in his Appendix S. I am unaware of the reason for this difference, but note the very small magnitude of the discrepancy and am content to use Mr. Hamilton's calculation. I thus arrive at the following quantification of Teva's share of the Generic Market during the Relevant Period:

	December 2005 - April 2007	**Inventory Adjustment**	**Ramipril sales in the "but for" world**
Total Ramipril Market Size	611,122,083		
Total Generic Market Size	374,092,845		
Teva Lost Sales	124,697,615	22,394,864	147,092,476

IX. Teva's Net Lost Profits

[221] The final step is to quantify Teva's losses. Leaving the economists, I turn to the experts who provided pricing and drug formulary information and to the expert accountants who prepared the final damages calculation. In general, lost profits on the sale of ramipril are calculated by multiplying the volume of lost capsules by the price and deducting expenses.

[222] To a large extent, the accounting experts agreed on many of the expenses, when one examines the closest scenarios to the "but for" world. Those are Ms. Loomer's Scenario 7, which has Teva entering with Apotex and another generic for an evaluation period of December 2005

to May 2, 2007, and Mr. Hamilton's Scenario 5, which runs from December 13, 2005 to April 27, 2007 with Teva, Apotex and an authorized generic entering the market on December 13, 2005.

[223] As noted at paragraphs 11(5) and11(6) above, by the end of the trial, only the following areas of disagreement remained:

a. the relevance and admissibility of portions of Ms. Loomer's reports regarding Teva's "lost business value" and "second ramp-up" – Sanofi brought a motion to strike these passages and my ruling on that motion appears in these Reasons;

b. the pricing of Teva's ramipril during the Relevant Period, having regard to the provincial formularies;

c. likely trade spend (including discounts and allowances) that would have been paid by Teva to pharmacists to stock Teva's ramipril;

d. likely price of API;

e. the reasonableness and quantification of any indirect losses, such as the loss of sales of other products;

f. the appropriate calculation of pre-judgment interest; and

g. recovery for unapproved indications, specifically, the HOPE indications.

[224] I will consider each of these issues in turn.

A. *Sanofi's motion to strike*

[225] Teva claims that it is entitled to compensation for any capital losses that it suffered during the relevant period. Teva submits that "lost business value" is a recoverable capital loss. To provide the Court with assistance, Ms. Loomer described and quantified this alleged loss.

[226] Sanofi objects to the inclusion of this amount in Teva's damages, arguing that the "lost business value" put forward by Teva is nothing more than a thinly-veiled claim for future profits. As the jurisprudence establishes that Teva is not entitled to any claim for losses incurred outside the Relevant Period, Sanofi asserts that these amounts should not be allowed.

[227] During the trial, before I had heard Ms. Loomer's testimony, Sanofi brought a motion to strike portions of the Expert Report in Chief and Responding Report of Ms. Suzanne C. Loomer. The impugned passages are:

1. From the Report in Chief: those passages related to "Lost Business Value" contained at paragraphs 230 to 310 and Appendix E and the column labeled "Lost Business Values" in the table under paragraph 28 and in Schedule 1 and related

portions of the graph in Schedule 2 and related portions of all appendices and schedules.

2. From the Responding Report:

- those passages related to “Lost Business Value”, consisting of paragraphs 57-73 and 88-91 and Appendix E and Appendix B, Schedules A1 and E3 and the row in the table under paragraph 76 labeled “Lost Business Value” and the column in the table under paragraph 96 labeled “Lost business Value” and related appendices and schedules; and

- those passages related to “ramp-up”, consisting of paragraphs 45-49, 77(d), 83-85, 90 (second sentence), Schedules 2-3, Appendix B, Schedule E5, and the row in the table under paragraph 50 titled “Duplicate Ramp-up adjustment” and all related appendices and schedules.

[228] After hearing oral submissions from the parties, I observed that, at that point in the trial, I had not heard Ms. Loomer explain her evidence or, more importantly, respond to questions on cross-examination. Nor did I have the benefit of hearing the evidence of Mr. Hamilton or Ms. Frederick, both of whom addressed various aspects of Ms. Loomer’s reports. Moreover, I was advised that Sanofi had already prepared and delivered the report of Ms. Frederick in response to Ms. Loomer and that Mr. Hamilton would be prepared to address portions of the impugned evidence, thereby reducing prejudice to Sanofi. At that stage, I felt unable to rule on

the admissibility of the evidence and advised the parties that I would reserve my ruling. During final argument, further submissions were made by both parties on the issue.

[229] For the reasons that follow, I will strike the impugned passages and have no regard to Teva's claim to "lost business value" or to the "second ramp-up".

[230] The basis of Sanofi's argument with respect to the impugned passages from both of Ms. Loomer's reports that relate to "lost business value" is that these statements or opinions are not relevant to the pleadings and are an abuse of process in view of: (a) the striking of the "permanent loss of market share" claims from Teva's counterclaim (see *Sanofi-Aventis Canada Inc v Teva Canada Ltd*, 2010 FC 1210, 377 FTR 293, aff'd 2011 FCA 149, 420 NR 115, leave to appeal to SCC refused, [2011] SCCA No 326 [*Sanofi 2010*]); and (b) the Federal Court of Appeal decision in *Alendronate (FCA)*, above.

[231] With respect to the "ramp-up" passages of Ms. Loomer's Responding Report, Sanofi argues that these passages suffer from the same problems as the "lost business value" passages and, in addition, they are not proper reply.

[232] In its response to this motion, Teva argues that the impugned passages are relevant to paragraphs 76 (h1)(ix), 143D, and 143G of its pleadings. Moreover, Teva, recognizing the limitations imposed by decisions of the Court in both *Alendronate (FCA)* and *Sanofi 2010*, submits that it has carefully restricted its case to a consideration of damages during the Relevant Period ending April 27, 2007.

[233] As the parties are well aware, the admissibility of expert evidence is governed by both Rule 279 of the *Federal Courts Rules*, SOR/98-106 and by the common law.

[234] The Supreme Court enunciated the common law principles governing the admissibility of expert evidence in *R v Mohan*, [1994] 2 SCR 9 at 20, [1994] SCJ No 36 [*Mohan*]. In addition to the well-established factors of relevance, necessity to the trier of fact, the absence of any exclusionary rule and a properly qualified expert set out in *Mohan*, the jurisprudence teaches that these factors must be weighed against the counterweights of consumption of time, prejudice and confusion (see e.g. *R v J-LJ*, 2000 SCC 51 at para 47, [2000] 2 SCR 600). Even where expert evidence is relevant, the trial judge may exclude it on the basis that any probative value is overborne by its prejudicial effect. Such matters as the efficient conduct of the trial and prejudice to the other party are certainly relevant to an assessment of admissibility.

[235] A second issue raised by Sanofi with respect to the portions of Ms. Loomer's Responding Report is that these passages are not proper reply. In *Halford v Seed Hawk Inc*, 2003 FCT 141, 24 CPR (4th) 220, Justice Pelletier very helpfully set out some guiding principles in respect of the admissibility of reply evidence. Of key importance to this motion, Justice Pelletier identified the requirement that the evidence sought to be admitted must be relevant to a matter in issue.

[236] In this motion, Sanofi does not dispute the qualifications of Ms. Loomer; nor does Sanofi identify any exclusionary rule that might apply. Moreover, I am prepared to accept that, if the evidence is otherwise admissible, it would assist me in this trial.

[237] This leaves relevance as the determinative criterion. Relevance is a threshold requirement for any evidence. *Sanofi 2010* and *Alendronate (FCA)*, above, have delineated boundaries on what evidence is relevant to the determination of s. 8 damages.

[238] The scope of a claim under s. 8 of the *PM (NOC) Regulations* was addressed by the Court of Appeal in *Alendronate (FCA)*. In that case, Apotex had pleaded that, under s. 8 of the *Regulations*, it was entitled to damages in respect of "lost sales and permanent market share" (see *Alendronate (FC)*, above at para 118 [emphasis added]). The Court of Appeal held that s. 8 does not include damages for "future losses", such as decreased market share due to delayed entry into the generic market. It is worthwhile repeating the determinative portion of the decision, at paragraphs 99 to 102:

> [99] According to the analysis of the Federal Court Judge, the losses claimed by Apotex were caused during the period since that is when Apotex was prevented from occupying the market and obtaining the market share which, based on its claim, it would otherwise have had. No one takes issue with this reasoning. The question is whether the decrease in sales which occurs in future years as a result of this decreased market share comes within section 8. The Federal Court Judge, by allowing the claim for losses "beyond May 26, 2005" to proceed, answered this question in the affirmative.
>
> [100] When regard is had to the broad grant of authority conferred by subsection 55.2(4) of the *Patent Act*, it seems clear that the measure of the compensation which can be awarded under the *PM(NOC) Regulations* is a matter within the discretion of the Governor-in-Council. It is also clear that in keeping with the purpose of the *PM(NOC)* Regulations and the balance which the *Patent* Act seeks to achieve, a range of compensation was open to the Governor-in-Council in the exercise of this discretion.
>
> [101] In this case, we have the advantage of knowing that in 1998 the Governor-in-Council focused on this very issue, and chose to limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of

> principle flows from this. The Governor-in-Council could have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.
>
> [102] The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period. I therefore conclude that the appeal should be allowed on this limited point.
>
> [Emphasis in original]

[239] Subsequent to that decision, in the context of the litigation now before me, Sanofi was successful in a motion to strike portions of Teva's pleadings (see *Sanofi 2010*). In *Sanofi 2010*, above, the Federal Court of Appeal affirmed decisions of a Prothonotary and Judge of this Court striking paragraphs of Teva's pleadings that claimed damages for "permanent loss of market share". The Court of Appeal, in its very short decision, followed *Alendronate (FCA)* and affirmed the decision to strike the impugned pleadings.

[240] In the motion on admissibility, Sanofi objects to consideration of both "lost business value" and "duplicate ramp-up adjustment".

(1) Lost business value

[241] The key to a decision on this question is the proper characterization of the lost business value calculation carried out by Ms. Loomer. If the losses claimed were suffered in subsequent years, although caused during the Relevant Period, they are not recoverable.

[242] In the impugned section of her Report in Chief, Ms. Loomer carries out calculations to determine "Lost Business Value" for Teva as at April 27, 2007. One example of the opinions that she expresses is seen at paragraph 236:

> Had the Alleged Actions by the Defendant not occurred, Teva Canada's business value as at the Valuation Date would have been higher than it actually was if the expected future cash flows for Teva Canada at the Valuation Date would have been higher.
>
> [Emphasis added]

[243] At paragraph 238, Ms. Loomer acknowledges that she has considered "the degree to which the losses would reasonably continue after the end of the relevant period" (emphasis added). In paragraph 238(a), she describes "Lost Profits on Sale of Ramipril". Both of these notions (along with others in the impugned passages) relate to losses that are properly described as future losses. However, throughout her reports, Ms. Loomer carefully relates such matters to April 27, 2007. The question that I am left with is whether there is any legitimate basis – in light of *Sanofi 2010* and *Alendronate (FCA)* – to incorporate "lost business value" into the calculation of damages. I conclude that there is not.

[244] Simply stated, the calculation performed by Ms. Loomer is a calculation of future lost profits. If she had been asked to quantify future lost profits, I cannot see how her calculations would have been any different. By capitalizing those lost profits to the last day of the Relevant Period, she does not, in my view, change the proper characterization of those amounts.

[245] Teva argues that, by using the valuation date of April 27, 2007, Teva is claiming for a loss within the Relevant Period. This argument does not overcome the fact that the loss relates to losses that do not arise until after April 27, 2007. The claimed losses – however named – fall squarely within the exceptions set out in *Alendronate (FCA)* and are not recoverable.

[246] The characterization of lost business value was considered by both Mr. Hamilton and Ms. Frederick. Ms. Frederick described the alleged losses as "the reduction in value based on Teva's lost future profits from April 27, 2007 onwards in perpetuity" (Exhibit 140 at para 37). Mr. Hamilton described Ms. Loomer's calculations as follows (Exhibit 162 at para 141) and concluded, therefore, that these losses should not be included in the calculation of Teva's losses during the Relevant Period:

> [T]he Loomer Report's estimate of lost business value is calculated based on the present value of Teva's estimated future losses of Teva-Ramipril after April 27, 2007. Therefore, the Loomer Report has included losses after the Delay Period (i.e. subsequent to April 27, 2007) in its estimate of Teva's losses.

[247] I accept the characterization of both Mr. Hamilton and Ms. Frederick. The claimed "lost business value" is a claim to future profits and not a recoverable loss under s. 8.

[248] I appreciate that, in this action, Teva has pleaded harm due to "[r]eduction in the overall value of the business due to being held off the market with respect to Teva's generic ramipril" (Seventh Amended Statement of Defence and Counterclaim at para 76(h1)(ix)). Sanofi did not move to strike this statement, in spite of the fact that it successfully moved to strike other paragraphs referring to future profits (see *Sanofi 2010*, above). The fact that Sanofi did not move to strike paragraph 76(h1)(ix) does not mean that that paragraph in the pleadings and the evidence allegedly related to it become relevant to a s. 8 claim. The problem with Teva's argument is that it ignores the reality that Sanofi could have had no idea of how Teva intended to "prove" lost business value. It is quite possible that, had Sanofi understood the scope of this pleading, it would have moved to strike it. Until Sanofi (and this Court) had an opportunity to review the evidence in support of this claim, the claim was capable of many interpretations. Only upon reviewing Ms. Loomer's expert report in light of all the evidence on this issue was everyone able to fully understand the meaning of this claim.

[249] Teva also argues that *Alendronate (FCA)* can be distinguished on the basis that lost business value was not pleaded in that case. Rather, Apotex pleaded only lost sales and loss of permanent market share, both of which clearly occurred outside the relevant period. Thus, Teva submits, the sole *ratio* that can be drawn from the Court of Appeal's decision is that a second person cannot claim for lost future sales and loss of permanent market share. That is exactly the problem with Teva's evidence; it is a claim for lost future sales or permanent market share, no matter how worded in the pleadings. The *ratio* of *Alendronate (FCA)* is directly applicable.

(2) Duplicate ramp-up adjustment

[250] The second aspect of Sanofi's motion deals with the "Duplicate Ramp-up adjustment" that first appeared in Ms. Loomer's Responding Report. At paragraph 83 of her Responding Report, she describes this concept as follows:

> In both the Hamilton and Loomer Statements, the Lost Sales of Ramipril during the Relevant Period, takes into account a ramp-up in volumes from zero to a sustained ongoing level (Run Rate). This same ramp-up in volumes was also experienced when Teva actually entered the market in 2007. Had Teva generated the Lost Volumes of Ramipril, it would not have experienced two periods of ramp-up volumes. Therefore, the duplicate ramp-up period should be eliminated.

[251] In general terms, as I understand it, the term "ramp-up" refers to the period of time that it takes a drug manufacturer after initial approval of its drug to reach its final level of sales. It takes some time to negotiate agreements with pharmacies and distributors, to acquire formulary listings and to physically move product to drug stores. In the "but for" world, both Mr. Hamilton and Ms. Loomer base their analyses on a ramp-up period of about two months beginning on December 13, 2005. In the actual world, once Teva came to market in late April 2007, it experienced a "real world" ramp-up. According to the calculations of Ms. Loomer, Teva took about 14 month months to reach its sustained level of sales. Teva, supported by Ms. Loomer, argues that this second ramp-up would not have existed had it been able to come to market in the absence of the *Regulations*.

[252] The loss claimed by Teva is the difference between what Teva would have sold had it been fully ramped up on April 27, 2007 and what it actually sold during the 14-month ramp-up

period. Initially, Ms. Loomer calculated this second ramp-up adjustment as $5.6 million. Based on Mr. Hamilton's correction, it appears that this amount, if claimable, would be $2.067 million.

[253] Although the value of the second or duplicate ramp-up period may well be characterized as a loss to Teva, it is a loss occurring after the Relevant Period. Once again, Teva comes up against the clear and unequivocal finding in *Alendronate (FCA)*.

(3) Conclusion on lost business value and duplicate ramp-up

[254] As in *Alendronate (FCA)*, both the "lost business value" and "duplicate ramp-up period" were caused during the Relevant Period since that is when Teva was prevented from occupying the market and obtaining the market share which, based on its claim, it would otherwise have had. Nevertheless, I am bound by the decision of the Court of Appeal to conclude that Teva is not entitled to these claimed losses. It follows that the impugned passages from Ms. Loomer's Report and Responding Report are irrelevant to the issue to be decided. The motion of Sanofi is allowed and the impugned portions of Ms. Loomer's reports are struck. As a consequence, no amounts in respect of duplicate ramp-up period or lost business value will be awarded.

B. *Pricing over the Relevant Period*

[255] To calculate Teva's gross losses over the Relevant Period, both Mr. Hamilton and Ms. Loomer took Teva's Lost Volumes and multiplied that volume by an average weighted cost of Novo-ramipril over the Relevant Period. The product of estimated volumes and the selling

price equals the estimated lost gross sales. The differences in their conclusions appear to relate to the input data provided by Mr. Palmer (to Mr. Hamilton) and Ms. Bacovsky (to Ms. Loomer).

[256] A quantification of Teva's Lost Volumes is set out above at paragraph 220.

[257] There is no disagreement that, in a multi-generic scenario for the Relevant Period, the average price for generic ramipril would be 63% of the brand price for the period December 13, 2005 to December 2006. In June 2006, Ontario enacted Bill 102, *Transparent Drug System for Patients Act*, 2nd Sess, 38th Leg, Ontario, 2006 [Bill 102]. Under this legislation, which came into force in late 2006, the reimbursement level for a generic could not exceed 50% of the price of the brand product.

[258] Ms. Loomer carried out the necessary calculations in her reports. She was instructed to assume a price of 63% of the brand price for ALTACE during any period where Teva was in competition with other generic manufacturers.

[259] Ms. Loomer calculated a "weighted average price per unit" for each strength and then multiplied the weighted average price by the total lost volumes by strength to arrive at the lost gross revenues (see Exhibit 28, vol 1 at para 82). Ms. Loomer concluded that, under her Scenario 7 (multi-generic, December 2005 to May 2, 2007), the weighted average gross selling price/unit would have been $0.59 (Exhibit 29, vol 1 at Schedule 1).

[260] Mr. Hamilton, under his Scenario 5 (multi-generic, December 13, 2005 to April 27, 2007), found a weighted average gross selling price of $0.56.

[261] In his Responding Statement (Exhibit 162, at para 42(a)), Mr. Hamilton opined that Ms. Loomer's weighted average calculations contained two errors. Only one of those errors is relevant to Ms. Loomer's Scenario 7 (three generics entering simultaneously in December 2005):

> Ms. Loomer overstated the weighted average price for the time period August 1 to November 30, 2006. This resulted from an overstatement of the weight assigned to the Ontario non-[Ontario Drug Benefit (ODB)] price as indicated in Loomer Report Schedule B7. The weight assigned to the Ontario non-ODB price should have been reduced by 16.2% to account for the weight assigned to the ODB price. This error results in a total weighted average price of 116.2%, rather than 100%, for August to November 2006.

[262] According to Mr. Hamilton, Ms. Loomer's prices in 2006 were higher than in 2005 due to this error, "which resulted in an increased price of approximately $0.04 in 2006" (Exhibit 162 at para 41(c)). When the corrected price for 2006 is plugged into the calculations, the result would be a downward adjustment to the overall weighted average price found by Ms. Loomer.

[263] Ms. Loomer did not provide a response to these alleged errors. Significantly, Ms. Loomer noted that her prices were "fairly in line with Mr. Hamilton" and that "pricing is not the culprit in terms of overall difference". Accordingly, subject to the discussion below with respect to Quebec pricing, I accept Mr. Hamilton's calculations to establish the overall weighted average price for the Relevant Period.

[264] In oral submissions, Teva stated that there was some dispute regarding the exact time at which Ontario's Bill 102 took effect. In particular, Teva says that there was evidence that no prices were reduced until early 2007. However, Teva did not base its estimates on that position, as its own expert (Ms. Loomer) indicated that she was asked to assume that Teva would have charged 50% of the brand price for ODB sales after October 1, 2006, and that she understood that Ontario's regulations were implemented "in or around October 1, 2006" (Exhibit 28, vol 1 at para 72(d), fn 18).

[265] With respect to pricing in Quebec, Mr. Hamilton explained that Ms. Loomer assumed that Quebec pricing changed to 50% after April 2007, whereas he assumed that the change occurred on April 1, 2007. Mr. Hamilton noted that, because the accounting ends on April 27, there is only a one month difference.

[266] While Mr. Hamilton's opinion finds some support in Mr. Palmer's report, it is unlikely that the price for Teva's ramipril product in Quebec would have been reduced prior to the end of the Relevant Period. In his report, Mr. Palmer explained that Quebec's guaranteed selling price (BAP-15) policy meant that price changes cannot normally be implemented until the next update of the province's Liste de Médicaments. According to Mr. Palmer, the next update after the implementation of Ontario's Bill 102 in October 2006 was not until April 2007 (Exhibit 62, vol 1 at para 90). However, Mr. Palmer also confusingly reported that Quebec did not change its pricing policy in response to Ontario's legislation until June 2007 (Exhibit 62, vol 1 at para 90). In addition, he testified that it took "a couple years" for Quebec prices to be brought in line with Ontario pricing, and that transitional measures were in place during that period. While

Mr. Palmer testified that “there was some discussion about [Quebec] being reimbursed” for the higher prices charged during the transition period, he had no first hand knowledge of that.

[267] On the whole, Mr. Palmer’s evidence suggests that it is more likely than not that Quebec’s prices did not change until after the Relevant Period, as the operation of BAP-15 clearly meant that there would be some time lag, and Mr. Palmer himself stated that it took two years for prices to conform. Mr. Palmer’s suggestion that the excess pricing may have been reimbursed at a later date is not supported by an adequate evidentiary basis.

[268] Overall, I am left with a somewhat confused record on this important consideration. However, it appears that Mr. Palmer’s results should have taken a higher price into account for Quebec for a portion of the Relevant Period. It follows that Mr. Hamilton’s overall weighted average price of $0.56/unit would need to be adjusted upwards to take this into account. Because of the other minor problems with Ms. Loomer’s calculations, the increase should be applied to the analysis and calculations provided by Mr. Hamilton.

C. *Trade spend*

[269] The parties are in disagreement as to the appropriate level of “trade spend” that must be deducted from Teva’s profits as an expense. During this trial, I heard much evidence related to what is referred to as “trade spend”. Trade spend encompasses allowances provided to pharmacists and the distribution allowance paid to wholesalers. For purposes of this part of the

decision, I have not addressed the items described as “free goods” and prompt payment discounts; there appears to be no dispute as to the valuation of those amounts.

[270] The calculation of Teva’s damages must take into account trade spend that would have been paid during the Relevant Period. The higher the trade spend, the lower the profit that Teva would have earned and the lower the award of damages. Each of Mr. Hamilton and Ms. Loomer was asked to incorporate trade spend into their calculations of damages on the basis that Teva would have been a sole generic manufacturer of ramipril and on the basis that there would have been other competitors in the market during the Relevant Period. Since I have concluded that Teva would have faced competition in the hypothetical market, I can ignore the sole generic calculations by each expert and focus on the level of trade spend for a multi-source market.

[271] One point that is not in dispute is that a manufacturer’s trade spend is much higher when it is selling a product into a multi-generic market. The reason is simple; in a multi-generic market, a company faces stiff competition to convince pharmacies and wholesalers to stock its version of a generic product.

[272] Ms. Loomer, in her Report, (see Exhibit 28, vol 1 at para 88ff) described her method to calculating an appropriate level of trade spend. Very helpfully, she provides a general description of trade spend as follows:

> 89. Tradespend, generally, is an allowance off of the formulary price that is given to pharmacies and wholesalers. The amount of Tradespend will vary by Customer. Various factors are considered by Teva in determining how much Tradespend to offer to a Customer, **[Redacted]**.

> 90. These discounts generally fall into a number of categories, but are referred to collectively herein as “Tradespend”. **[Redacted]**

[273] Ms. Loomer examined a number of Teva documents showing total trade spend that Teva had paid during the period 2002 to 2010 on all of its products and based her opinions on these figures. Her approach (described in Exhibit 28, vol 1 at para 98) for a multi-source market can be summarized as follows:

1. Multiply the Lost Gross Sales of Ramipril by the **[Redacted]** prompt payment discount and then multiply this by the Take-up Rate for all of Teva’s products for the corresponding fiscal year.

2. Multiply the Lost Gross Sales of Ramipril in each date increment by the **[Redacted]** Distribution Allowance and then multiply this by the proportion of total sales that Teva made to wholesalers for all of Teva’s products for the corresponding fiscal year.

3. Multiply the Lost Gross Sales of Ramipril by the trade spend rate for all other discounts where the trade spend rate is reflective of average rates charged for non-Single-Source products.

4. As reflected in Schedule B23 to her Report, the trade spend for the years included in the Relevant Period was: **[Redacted]** in 2005; **[Redacted]** in 2006 and **[Redacted]** in 2007.

[274] Mr. Hamilton was asked to assume a trade spend rate of **[Redacted]** of sales for a sole generic and **[Redacted]** in a multi-generic market (Exhibit 161, vol 1 at para 51). Mr. Hamilton assessed the reasonableness of these assumptions against Teva's actual trade spend for all products for the years 2003 to 2007 (Exhibit 161, vol 1 at para 52), which he found to be **[Redacted]**. He also reviewed the Loomer Report. In Mr. Hamilton's opinion Teva's actual trade spend percentage relating to its ramipril sales between 1999 and July 31, 2008 was equal to **[Redacted]**. Based on his review, Mr. Hamilton concluded that **[Redacted]** in a competitive environment was reasonable. This rate is higher than those shown by Ms. Loomer for the relevant years.

[275] I question the inclusion by Mr. Hamilton of the later years in his reasonableness assessment of trade spend. Mr. Fishman, Dr. Sherman, Ms. Decelles and Mr. Doug Sommerville, who is Teva's vice president of marketing and sales, all testified that trade spend rates have increased over the past few years. Given this evidence, the inclusion of data beyond 2007 may skew the level of trade spend higher.

[276] I conclude that a level of **[Redacted]** for the entire Relevant Period is a reasonable approximation of the trade spend that would have been paid.

D. *Price of the active pharmaceutical ingredient*

[277] The calculation of Teva's damages must take into account the cost of materials used to produce Novo-ramipril in the Relevant Period. Stated simply, the higher the cost of materials, the

lower the profit that Teva would have earned, and the lower the award of damages. One area of disagreement between Mr. Hamilton and Ms. Loomer was the cost at which Teva could have acquired ramipril API during the Relevant Period. Mr. Hamilton explained his API pricing assumption as follows (Exhibit 161, vol 1 at para 72):

> I have assumed that the weighted average price paid by Teva for ramipril [API] in 2006 and 2007 is representative of the price Teva would have paid for ramipril in the years 2003 to 2007. I applied the average US$/CDN$ exchange rate for each respective year to this weighted average price in estimating the cost of ramipril in each year as the ramipril invoices were denominated in US dollars.

[278] In paragraph 78 of his report (Exhibit 161, vol 1), Mr. Hamilton stated that, for Teva's weighted cost of ramipril for 2006 and 2007, he used a cost of **[Redacted]**. Mr. Hamilton also acknowledged that, if he had used an API cost of **[Redacted]**, there would need to be a reduction in incremental cost of sales (and, hence, an increase in lost incremental profits) of **[Redacted]**.

[279] Ms. Loomer provided two API prices: **[Redacted]** if Teva were sole source and **[Redacted]** for multi-source scenarios (Exhibit 28, vol 1 at para 138(c)):

[Redacted]

During cross-examination, Ms. Loomer acknowledged that she did not make any independent investigations into the market for ramipril API during the Relevant Period.

[280] Teva submits that Mr. Hamilton arbitrarily selected purchases in 2006 and 2007, thus inflating the price for API. Teva points out that the inclusion of 2007 and 2008 – as was done by Ms. Loomer – results in a lower API average price.

[281] I do not find Mr. Hamilton's use of 2006 and 2007 to be "arbitrary". In the 2006 to 2007 period, Teva was competing with other generics in a multi-source market, as it would have been in the "but for" market. The price drop in late 2007 appears to have been related to global expansion of ramipril sales, including the entry of generics into the US ramipril market **[Redacted]**. That is an event that would not have occurred in our "but for" world. Hence it was reasonable of Mr. Hamilton to base his estimate of API cost on the real world experience of Teva in 2006 and 2007, as that period more closely resembles the competitive landscape in the "but for" world.

[282] I prefer Mr. Hamilton's approach to the pricing of API and accept his estimated cost of **[Redacted]** throughout the Relevant Period.

E. *Indirect losses*

[283] Teva claims that it is entitled to recover for certain indirect losses. In particular, Teva argues that it should be permitted to recover for lost profits on sales of other Teva products that it could have made and for lost return on equity. Ms. Loomer included both of these amounts in her calculations.

(1) Lost profit on sales of other Teva products

[284] The lost profits on sales of other Teva products was described by Mr. Sommerville in his testimony. As Mr. Sommerville stated, being first in the market allows Teva to leverage

additional business and additional profitability. I have no reason to doubt that he is right; there is a strong element of common sense to his assertion. However, assuming that he is correct and that the amount could in some way be quantified, the problem is that, in the "but for" world that I have constructed, Teva is not first to market. Accordingly, on the evidence before me, I have no support for Ms. Loomer's loss under this head of damages.

[285] Although Ms. Loomer includes an amount for this alleged loss, her Report describes this loss only in the context of a single source market for Teva' ramipril. She does not explain how this loss would or could arise in the multi-generic world.

[286] Even if I were to accept a hypothetical world where Teva was alone on the market, I have nothing beyond the vague statements of Mr. Sommerville about Teva's ability to leverage additional business in the marketplace. Before I award damages in the millions of dollars, I would want to see something more concrete and measurable.

[287] The claim for lost profits on sales of other Teva products is disallowed.

(2) Lost indirect profit

[288] In her Responding Report, Ms. Loomer describes "lost indirect profit" as follows (Exhibit 29, vol 1 at para 51):

> If the Court finds that Teva would have entered the market and begun selling ramipril during the Relevant Period, but for the Alleged Actions of the Defendant, then Teva has been denied the ability to use and reinvest the profits that would otherwise have

> been available to it over the Relevant Period, and up to the date of trial.

[289] Both Mr. Dan Youtoff and Mr. Fishman testified that revenue from the sale of Novo-ramipril during the Relevant Period would have been put towards building more value into Teva, for example, through investing in research and development and litigation.

[290] I agree with Sanofi that this head of damages is unrecoverable for the reason that the alleged losses are speculative and too remote.

[291] As stated by Sanofi:

> The head of damages is analogous to a lost opportunity to enjoy the increased value of a failed second real estate transaction in *Kienzle v. Stringer* [(1981), 35 OR (2d) 85 at paras 19-24 (CA)]. In that case, the plaintiff sued the defendant lawyer for negligently certifying that the plaintiff had a good title on the first property. The plaintiff purchased a second property conditional upon his being able to sell the first property. Due to the title defect, the plaintiff could not complete the sale of the first property and the purchase of the second. The plaintiff claimed damages for the lost profit on the increased value of the second property. The Ontario Court of Appeal rejected the claim, finding that such loss is too remote.

[292] In addition, there is simply no evidence on the record, beyond the bare assertions of Mr. Fishman and Mr. Youtoff, that Teva would have made such investments. The claim is too vague and unsubstantiated to be allowable on the facts of this case. In his Responding Report, Mr. Hamilton commented (Exhibit 162 at para 130) that:

> Teva did not identify or produce any supporting documentation related to the specific business opportunities that Teva was not able to undertake over the Relevant Period due to the lost profits on the sale of Teva-Ramipril and other products.

[293] Finally, on this point, pre-judgment interest is the accepted method for compensating for this loss. As pointed out by the Supreme Court of Canada in *VK Mason Construction Ltd v Bank of Nova Scotia*, [1985] 1 SCR 271 at 286, [1985] SCJ No 12, "[i]nterest is the court's way of compensating . . . for the loss of the opportunity to invest that money" (see also *Seaboard Life Insurance Co v Bank of Montreal*, 2002 BCCA 192 at paras 89-91, 166 BCAC 64). Unless a plaintiff provides clear and non-speculative evidence of a lost opportunity that would exceed the interest otherwise payable on the lost sales, it appears to me that interest is the only remedy available to the plaintiff.

[294] In sum, the claim for lost indirect profits is not allowed.

F. *Pre-judgment interest*

[295] While both parties agree that Teva is entitled to pre-judgment interest, they disagree on the methodology for calculating the interest. Teva submits that pre-judgment interest should be calculated in accordance with the method utilized by Ms. Loomer, both as to time and rate.

[296] Ms. Loomer only calculated interest from the end of the Relevant Period, explaining as follows:

> Q. Next is lost indirect profit and pre-judgment interest, can you tell us about that?
>
> A. In my report I calculate two components to this. I calculate lost [indirect] profit during the relevant period and then I calculate pre-judgment interest on the loss from the end of the relevant period up to today.

> Mr. Hamilton equates lost indirect profit to pre judgment interest throughout the relevant period and up to, I think, it was August 2011 was his cut off.

[297] As set out above (see para 294), I have disallowed Teva's claim for lost indirect profit, on the basis that pre-judgment interest is intended to compensate Teva for its lost indirect profits (as described by Ms. Loomer). Accordingly, it is appropriate to include pre-judgment interest to Teva from the commencement of the Relevant Period up to the date of judgment.

[298] Ms. Loomer calculated pre-judgment interest at a single fixed rate equal to the rate in effect on May 1, 2007 under Ontario's *Courts of Justice Act*, RSO 1990, c C43 [*Courts of Justice Act*].

[299] Mr. Hamilton calculated pre-judgment interest from December 13, 2005. However, Sanofi instructed Mr. Hamilton to calculate pre-judgment interest "based on the Ontario Courts of Justice Act quarterly rates in effect from the date Teva alleges its losses first began to August 31, 2011 on a simple basis" (Exhibit 161, vol 1 at para 125). In other words, Mr. Hamilton's calculation of the rate of interest varied from quarter to quarter. Mr. Hamilton acknowledged that, typically, "what one does is select the rate in which the cause of action arose and apply that throughout the period". That is the preferred approach.

[300] I conclude that pre-judgment interest should be calculated from December 13, 2005 at the rate in effect under the *Courts of Justice Act* at that date.

G. *HOPE indications*

[301] Sanofi submits that the “loss” referred to in s. 8 of the *PM (NOC) Regulations* does not contemplate recovery by a second person for sales attributable to an unapproved indication or use. Thus, Sanofi argues, the damages awarded to Teva should include a “downward significant adjustment” to reflect sales of Novo-ramipril that would have been attributable to the HOPE indications.

[302] One of the last steps in a drug approval process is the finalization of the product monograph. The product monograph, in part, sets out the uses or indications for which the drug is intended. The NOC issues with reference to the product monograph. From time to time, negotiations take place between Health Canada and a generic manufacturer as to what the approved indications will be. We know that Teva amended its proposed product monograph in August 2005 to eliminate what are known as the HOPE indications. Mr. Windross spoke to a product monograph for Novo-ramipril revised on August 26, 2005, and agreed that at that time, Teva decided that it would make allegations and would not seek approval for the HOPE indications. In our hypothetical world, it is likely that Teva’s final product monograph, as of December 13, 2005, would not have included reference to anything other than hypertension. In other words, as of December 13, 2005, Teva would likely have launched its Novo-ramipril with no reference to the use of ramipril to treat proteinuaria ('948 Patent) or the HOPE indications ('549 and '387 Patents). As we know, Sanofi had listed these patents on the Patent Register.

[303] Sanofi, in its pleadings, claims that Teva is not entitled to damages because “Teva’s ramipril product is only approved for the treatment of hypertension” (Fifth Amended Reply and Defence to Counterclaim of Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland GmbH at paras 62, 76). In its reply, Teva admits that allegation (Teva’s Third Amended Reply to Defences to Counterclaim at para 3).

[304] By Order dated November 25, 2011, this Court dismissed an appeal from an Order of Prothonotary Aalto, in which decision he had denied a motion by Sanofi to amend its pleadings to include specific reference to the HOPE indications. In the reasons for the Order, I stated that Sanofi was not precluded from presenting its legal argument that s. 8 does not contemplate recovery of damages in respect of lost sales of a generic product for an unapproved indication.

[305] From the evidence presented and the arguments before me in this trial, it is clear that the factual context of Sanofi’s argument is specifically the HOPE indications.

[306] Three clinicians were put forward as experts. Drs. Lin, Clark and Brophy provided great assistance in understanding the HOPE indications, drugs useful in the treatment and prevention of cardiovascular events and the prescribing practices of physicians.

[307] As described by the experts and witnesses, the HOPE study was a Canadian-led study, apparently undertaken with the involvement of Sanofi’s predecessor company, Hoechst Marion Roussell Canada Inc. The study assessed the role of ramipril in patients who were at high risk for cardiovascular events but who did not have left ventricular dysfunction or heart failure (Exhibit

153 at Tab 4: The Heart Outcomes Prevention Evaluation Study Investigators, “Effects of an Angiotensin-Converting-Enzyme Inhibitor, Ramipril, on Cardiovascular Events in High-Risk Patients” (January 20, 2000) 342:3 NEJM 145 at 145 [NEJM]). The investigators found that ramipril was “beneficial in a broad range of patients without evidence of left ventricular systolic dysfunction or heart failure who are at high risk for cardiovascular events” (NEJM, above at 150). In particular, the investigators reported that “[t]reatment with ramipril reduced the rates of death, myocardial infarction, stroke, coronary revascularization, cardiac arrest, and heart failure as well as the risk of complications related to diabetes and of diabetes itself” (NEJM, above at 150). Thus, the term “HOPE indications” has come to be associated with the patient profiles from the HOPE study where vascular protection was demonstrated.

[308] The results of the HOPE study were first presented in August 1999 at the European Society of Cardiology meeting in Barcelona, and later reported in the January 20, 2000 edition of the New England Journal of Medicine (Exhibit 153 at fn 4 and Tab 4). From that point, Mr. Gravel testified, sales of ALTACE increased quite dramatically.

[309] As shown in the table at paragraph 31 of these Reasons, Sanofi did protect any claim to the use of ALTACE for the HOPE indications until 2005, when the two HOPE Patents were granted and Sanofi obtained two listings on the Patent Register. By that time, the rate of increase of sales of ALTACE had reverted to its pre-HOPE levels.

[310] While the parties disputed the points at which the HOPE study impacted ramipril sales, it is more likely than not that some sales of ramipril during the Relevant Period would have related to the HOPE indications. The question is whether Teva can recover for those sales.

[311] Sanofi submits that Teva is not entitled to recover in respect of ramipril sales during the Relevant Period that would have been made to address the HOPE indications. This, Sanofi says, is because Teva did not address the HOPE Patents, having instead chosen to withdraw those indications from its product monograph in August 2005 and to withdraw the portions of its notice of allegation relating to the HOPE Patents on December 15, 2006. Thus, Sanofi argues, Teva would have had no entitlement to make sales of Novo-ramipril for the HOPE indications during the Relevant Period and therefore cannot now claim a loss attributable to those sales.

[312] While Sanofi's argument has logical appeal, it is not supported by the facts or – in my view – the law, which demonstrate that sales of generic drugs for unapproved or "off-label" indications can and do, legally, take place. There are a number of arguments that run counter to Sanofi's submission:

- the fact that generic manufacturers do not promote drug products for specific indications;

- the fact that off-label prescribing and substitution take place;

- the fact that, in the real world, Sanofi did not oppose the listing of Novo-ramipril as fully interchangeable with ALTACE; and

- the availability to Sanofi of an action for patent infringement with respect to the HOPE Patents.

I will discuss each of these.

[313] First, I observe that generic products are not promoted for specific uses, but are instead sold as drug products. Teva's position is supported by the testimony of Dr. Sherman, who stated that removing the HOPE indications from Apotex's product monograph "really had no relevance because we don't promote for an indication in any event". Dr. Sherman explained that Apotex does not promote products to physicians, so the indications in its monograph have no commercial relevance.

[314] Second, both Dr. Lin and Dr. Clark testified that they engage in "off-label" prescribing, or the prescription of a product for a use that is not set out in a product monograph. Indeed, Dr. Lin testified that general practitioners commonly prescribe products for non-approved indications based on medical literature, continuing medical education seminars, and the opinion of experts. Dr. Clark similarly reported that nephrologists rarely read product monographs, which "may be somewhat biased", and instead know of indications from the literature. According to Dr. Lin, "off-label" prescribing is an accepted practice (Exhibit 153 at paras 46-48). There appears to be nothing "illegal" about off-label prescribing.

[315] With specific reference to ramipril, Dr. Lin reported that general practitioners generally assume that generic ramipril products are therapeutically equivalent to ALTACE in every respect, and therefore that generic ramipril products can be used for the same uses as ALTACE. It is also significant that Dr. Lin testified that he does not write “no substitutions” on ALTACE prescriptions, because he believes pharmacists will dispense a generic version anyway.

[316] On the other hand, Dr. Brophy stated that he would prescribe ALTACE, rather than a generic, for the HOPE indications because the indication for the generic is the treatment of hypertension. Moreover, Dr. Brophy stated that, where he works, most pharmacists dispense ALTACE if the prescription says “ALTACE”, and “occasionally you actually do write no substitution”.

[317] Dr. Brophy’s testimony seems to be at odds with the other evidence before me. It seems that a significant number of physicians would have prescribed generic ramipril for the HOPE indications during the Relevant Period, even if those indications were not included in the generic’s product monograph. While I did not hear evidence from any front-line pharmacist, I am prepared to accept that the more usual practice would be for the pharmacist to substitute, even where ALTACE is written on the prescription. As Dr. Lin pointed out, this result would have likely occurred in any event as a result of mandatory generic substitution.

[318] While Sanofi argues that it would have opposed the listing of Teva’s ramipril product as fully interchangeable with ALTACE, that submission is not supported by the evidence of Sanofi’s actions in the real world. Specifically, I have no evidence that, at the time when

Novo-ramipril was actually launched in 2007, Sanofi opposed the listing of Teva's ramipril product as fully interchangeable. It is also telling that Sanofi did not require its AG to obtain a limited listing for its product.

[319] It is, therefore, more likely than not that Teva would have been able to make sales for the HOPE indications during the Relevant Period, without objection. It follows that any sales made during the Relevant Period which were solely related to the HOPE indications are still lost sales that Teva would have made in the absence of Sanofi's prohibition order, and losses for which Teva is entitled to recover under s. 8.

[320] Contrary to Sanofi's assertions, this does not lead to an "absurd" or "unintended" result by allowing a second person to circumvent the *Regulations*, which Sanofi says seek to preclude the infringement of listed patents. This is because, as Teva points out, generic products are not promoted for specific uses but rather sold as drug products, and the HOPE Patents are not at issue in this proceeding. If Sanofi believes that Teva is infringing or inducing infringement of the HOPE Patents, then Sanofi has a cause of action under the *Patent Act*. In that regard, I note that, since Teva and other generics began selling generic ramipril, Sanofi – who is no stranger to litigation – has not brought an action against any of the manufacturers for infringement of the HOPE Patents.

[321] Even if Sanofi is correct, and s. 8 prevents a second person from recovering for sales for an unapproved use, there is insufficient evidence to merit a reduction of Teva's damages on the facts of this case. Teva rightly points out that it would be impossible to determine how many

patients were prescribed ramipril solely for the HOPE indications without access to confidential patient records. This contention is supported by the testimony of Dr. Lin and Dr. Brophy, who both stated that it would be very difficult to accurately distinguish between patients taking ramipril for HOPE indications, hypertension, ventricular dysfunction, or some combination without accessing their confidential records.

[322] I conclude, therefore, that Teva is not precluded from recovering losses associated with the HOPE indications. That is not to say that a second person may always recover for unapproved indications. Another s. 8 claim may provide a different set of facts that warrants a different finding or a downward adjustment to the second person's damages pursuant to s. 8(5) of the *Regulations*. But, not in this case.

X. Conclusion

[323] In concluding, I would like to make a general comment. As noted at the beginning of these Reasons, right after the trial of this matter, I heard a companion case in Court File No. T-1357-09. There are obviously many similarities between the two cases. However, each case proceeded separately, with a different record. I wish to assure the parties and the readers that my decision in each case was made completely on the basis of the arguments made and the records before me in the applicable case.

[324] Having addressed all of the issues before me, I am quite disappointed that I cannot finalize a quantum of damages. However, I am hopeful that Sanofi and Teva, with the capable

assistance of their lawyers and experts, can quickly agree on a final amount to be paid by Sanofi to Teva based on these Reasons for Judgment. Indeed, during the trial, counsel for both parties repeatedly reassured me of their willingness to co-operate in this regard.

[325] In summary, the key findings that I have made, on the basis of the record before me, are as follows:

1. The Relevant Period for the determination of Teva's Lost Profits commences on December 13, 2005 and ends on April 27, 2007.

2. The Ramipril Market during the Relevant Period would have been 611,122,083 capsules.

3. The Generic Market during the Relevant Period would have been 374,092,845 capsules.

4. Teva would have entered the market simultaneously with an authorized generic and Apotex, with each participant sharing the Generic Market equally. As a result, Teva's Lost Volumes would have been 147,092,478 capsules.

5. With respect to the calculation of Teva's Net Lost Profits:

    - evidence of lost business value and duplicate ramp-up period is excluded;

- other than an adjustment to account for pricing in the province of Quebec (as discussed above), Mr. Hamilton's overall weighted average price of $0.56/unit should be applied;

- the deduction for trade spend should be calculated as **[Redacted]** for the entire Relevant Period;

- a price of **[Redacted]** for API should be applied;

- no amount should be allowed for lost profits on sales of other products;

- no adjustment should be made for lost indirect profits; and

- no adjustment should be made in respect of unapproved indications.

6. Pre-judgment interest should be calculated from December 13, 2005 at the rate in effect under the *Courts of Justice Act* as at that date.

[326] In addition, there is the question of costs. I would hope that the parties can agree on costs. In the event that the parties cannot agree on the amount of costs by June 15, 2012, they may make submissions to this Court, such submissions not to exceed ten pages. The parties will have a further 15 days to make reply submissions, if they choose, not to exceed five pages.

[327] I wish to express my gratitude to counsel for their diligence, competence and professionalism throughout the pre-trial matters and the trial. Thank you.

POSTSCRIPT

[1] The Confidential Reasons for Judgment were released to the parties on May 11, 2012. Upon release of the Confidential Reasons, the parties were requested to advise the Court of portions of the Reasons and Judgment that they wished redacted for the Public Reasons. This version of the reasons contains redactions of small portions of the Confidential Reasons for Judgment.

[2] In general terms, Court proceedings should be open and accessible. This general principle obviously applies to any reasons for judgment and judgments issued by this Court. I accept that an exception may be made where risks to a party of the release of sensitive commercial information outweigh any public interest in having access to that information. However, it is important that the redacted reasons permit the reader to understand the context and, thus, the reasoning of the Court.

[3] Sanofi was reasonable in its request; I have accepted that all of the suggested redactions will be incorporated into the Public Reasons.

[4] Teva seeks much more extensive redactions, stating only that it wishes “to maintain the confidentiality of its information, all of which was protected under the Protective Order [dated

October 21, 2010]". I note first that the Protective Order was never intended to provide a cloak of silence forever. Teva does not attempt to explain why certain information remains commercially sensitive or prejudicial.

[5] Nevertheless, I have reviewed each of the redactions proposed by Teva. For each proposed redactions that I am prepared to allow, I am satisfied that the risks to a party of the release of the sensitive commercial information outweigh any public interest in having access to that information. The accepted redactions include evidence with respect to matters such as levels of trade spend or the pricing of API. Even with the redactions, I believe that a reader is able to understand the nature of the evidence and the reasoning applied to reach the relevant finding. The proposed redactions that I have rejected consist of information that is historic or general in nature or that is integral to my reasoning. In any event, I am not persuaded that the disclosure of any of the information would result in prejudice to Teva that is not outweighed by the public interest in having those portions of the Reasons and Judgment in the public domain.

"Judith A. Snider"
Judge

Ottawa, Ontario
Public Reasons – May 23, 2012
Confidential Reasons - May 11, 2012

Appendix A – List of Witnesses

I. List of Witnesses

A. *Plaintiff's fact witnesses*

(1) Mr. Barry **Fishman**

Mr. Barry Fishman is the president and chief executive officer of Teva Canada. Mr. Fishman spoke to a number of topics including: Teva's position in and the nature of the Canadian generic pharmaceutical market; the "first mover advantage"; the actions Teva would have taken in various hypothetical scenarios; and Teva's actual experience with ramipril and with other significant molecules.

(2) Mr. Dan **Youtoff**

Mr. Dan Youtoff is a chartered accountant and the senior director, corporate accounting at Teva. Mr. Youtoff testified regarding Teva's financial statements and the effect that the launch of ramipril in 2003 would have likely had on Teva's finances; Teva's financial relationship with Teva Israel; and trade spend.

(3) Mr. Brad **Laviolette**

Mr. Brad Laviolette is Teva's senior director of finance, North America, for technical operations. Mr. Laviolette spoke about Teva's capacity, production costs, and the source and price of API for Novo-ramipril.

(4) Mr. David **Windross**

Mr. David Windross was president of government and professional affairs for Teva in 2000, and was also responsible for regulatory affairs between 2001 and 2006. His testimony related to the development of Novo-ramipril; the drug submission and formulary listing processes; the indications for Novo-ramipril; and the actions Teva would have taken had it obtained an NOC in 2003.

(5) Mr. Doug **Sommerville**

Mr. Doug Sommerville is vice president of marketing and sales for Teva. Mr. Sommerville discussed the significance of single source products; Teva's reputation and finances; the actual launch of Novo-ramipril and the losses resulting from Teva's delayed market entry; the generic market, including discounts and formulary listing; and Teva's business model.

(6) Dr. John Kane **Denike**

Dr. John Kane Denike was manager of Teva's patent department from 2000 to 2002, at which time he joined ratiopharm, where he served as director of patent legal and regulatory affairs until 2007. Dr. Denike discussed Teva's business strategy; the company's actual ramipril strategy as well as the actions it would have taken had it obtained an NOC in 2002; authorized generics, including ratiopharm's experience as the authorized generic for ramipril; and formulary submissions.

(7) **[Redacted]**

[Redacted] is the head of **[Redacted]** North American API division, and the account manager for Teva. **[Redacted]** testified regarding the prices at which **[Redacted]** sold ramipril to Teva, the price that would have applied in the "but for world", as well as the factors that affect price. In addition, **[Redacted]** discussed **[Redacted]** ability to supply ramipril to Teva and the nature of the ramipril API.

B. *Plaintiff's expert witnesses*

(1) Dr. William Foster **Clark**

Dr. William Foster Clark was qualified by the Court as a practicing clinician in nephrology and a Professor of Medicine with expertise in nephrology and the use of pharmaceuticals. Dr. Clark spoke to a number of topics including the uses of ramipril, including with respect to the HOPE indication and proteinuria; the practice of "off-label" prescribing; and the treatment of hypertension.

(2) Dr. James M. **Brophy**

Dr. James M. Brophy was qualified by the Court as a Professor of Medicine and Epidemiology, and a cardiologist with expertise in clinical cardiology, cardiovascular epidemiology, pharmacoepidemiology and drug safety, and the evaluation of health technologies. Dr. Brophy provided opinions on the HOPE indication and prescribing practices with respect to that indication, as well as the most common uses of ramipril.

(3) Ms. Karen **Friedman**

Ms. Karen Friedman was qualified by the Court as a pharmaceutical industry consultant with expertise in pharmaceutical regulatory affairs in Canada. Ms. Friedman provided her opinion as to which Sanofi products that became generic after 2000 may have had an authorized generic.

(4) Ms. Suzanne C. **Loomer**

Ms. Suzanne C. Loomer was qualified by the Court as a chartered accountant and chartered business valuator with expertise in business valuation and damages quantification. Ms. Loomer provided opinions on the quantification of Teva's losses.

(5) Ms. Rosemary **Bacovsky**

Ms. Rosemary Bacovsky was qualified by the Court as a pharmaceutical industry consultant and pharmacist with expertise in formulary listing, market access, reimbursement policies and pricing regimes of the Canadian pharmaceutical marketplace. Ms. Bacovsky discussed provincial drug plans, the formulary listing process, and provincial pricing and interchangeability regimes.

(6) Dr. Aslam H. **Anis**

Dr. Aslam H. Anis was qualified by the Court as an economist with expertise in markets for pharmaceutical products in Canada. Dr. Anis opined on the first-mover advantage; erosion curves; growth of the ramipril market in the but for world; the difference between econometric modelling and time-series forecasting; the impact of the HOPE study; and Teva's market share in various hypothetical scenarios.

C. *Defendant's fact witnesses*

(1) Mr. Jean-François **Leprince**

Mr. Jean-François Leprince was president and chief executive officer of Hoechst Marion Roussel Canada Inc. (Hoechst) from 1998 until early 2000. Following the transition of Hoechst into Aventis Pharma Inc. (Aventis), Mr. Leprince retained the position of president until the end of 2004. After the acquisition of Aventis by Sanofi, Mr. Leprince remained the advisor and consultant to the company's new chief executive officer until 2005. Mr. Leprince testified regarding Sanofi's approach to ALTACE since 1998; and the actions Sanofi either contemplated or hypothetically would have taken in response to the genericization of the ramipril market at various times, particularly with respect to the launch of an authorized generic and the promotion of ALTACE.

(2) Mr. Benoit **Gravel**

Mr. Benoit Gravel is vice president of sales for Sanofi. He first joined one of Sanofi's predecessors in 1987. Mr. Gravel became involved with ramipril in 2000 as vice president of commercial affairs, and was responsible for marketing and sales of ALTACE until 2005. Mr. Gravel discussed Sanofi's response to the possibility of generic entry into the ramipril market, as well as the steps Sanofi would have taken to prepare for generic entry in the "but for" world; the launch of an authorized generic for ramipril; and the promotion of ALTACE in the real and hypothetical worlds. Mr. Gravel also discussed Sanofi's approach to the various patents for ramipril, and Sanofi's actions with respect to the HOPE indications.

(3) Ms. Anne **Bowes**

Ms. Anne Bowes is the director of the Office of Patented Medicines and Liaison, as well as interim director of Submission and Information Policy Division. Ms. Bowes testified regarding the drug submission and NOC process and the submissions made by various suppliers of generic ramipril.

(4) Mr. Olivier St. **Denis**

Mr. Olivier St. Denis is Riva's executive vice president of business development. Mr. St. Denis spoke to a number of topics including the indications for Riva's ramipril product; the cross-license between Riva and Pharmascience; the actions Riva would have taken had it gained market entry in 2004; and Riva's presence outside of Quebec.

(5) Ms. Franca **Mancino**

Ms. Franca Mancino is a director with Sanofi and is responsible for regulatory affairs and pharmacovigilance. She has been employed by Sanofi or its predecessors since 1993. Ms. Mancino discussed her involvement in regulatory activities related to ALTACE; authorized generics; the indications for ALTACE; and Sanofi's patent listings with respect to ALTACE.

(6) Dr. David **Goodman**

Dr. David Goodman is the CEO of Pharmascience. He spoke to a number of topics, including the actions Pharmascience would have taken had Riva obtained an NOC in 2004 or if Pharmascience had been the sole generic; Pharmascience's cross-licenses with Riva; Pharmascience's ability to supply the Canadian market for ramipril from 2004 onwards; and the price of API and other ingredients for ramipril.

(7) Ms. Manon **Decelles**

Ms. Manon Decelles is Sanofi's director of business development and acquisitions. She was involved in the launch of an authorized generic for ALTACE, and described her work in that area, as well as Sanofi's practice with respect to authorized generics.

(8) Mr. Bob **Woloschuk**

Mr. Bob Woloschuk was the vice president of business development for ratiopharm from early 2003 until August 2010, and was then employed by Teva in an integration role from until October 2010. Mr. Woloschuk described ratiopharm's reasons for becoming an authorized generic for ramipril, the company's agreement with Sanofi, the launch of its product, and subsequent amendments to the agreement. Mr. Woloschuk also discussed the profitability of authorized generics, including ratiopharm's ramipril product, and trade spend in the generic ramipril market.

(9) Mr. Brent **Fraser**

Mr. Brent Fraser is the director of drug program services with the Ontario Public Drug Programs, within Ontario's Ministry of Health. He has held that position since 2005, having joined the Ministry in 1997. Between 2002 and 2005, Mr. Fraser was the associate director of pharmaceutical services coordination, and then director of the drug system secretariat. In his testimony, Mr. Fraser discussed Ontario's formulary, pricing, interchangeability, reimbursement and drug submission regimes. Mr. Fraser also spoke to the regulation of rebates and professional allowances.

(10) Dr. Bernard Charles **Sherman**

Dr. Bernard Charles Sherman is chairman and chief executive officer of Apotex and related companies. Dr. Sherman testified regarding Apotex's regulatory submissions, formulary listing dates, and litigation in respect of ramipril; the impact of delayed formulary listing on price; and the product monograph for Apo-ramipril. Dr. Sherman also discussed Apotex's capacity and sales of Apo-ramipril, as well as the steps Apotex would have taken had it received its NOC as of April 26, 2004, and Dr. Sherman's patent application for ramipril. In addition, Dr. Sherman described the generic market; authorized generics; trade spend and pricing for single source products; and lost sales of other products and reputational loss. Dr. Sherman also testified to the hypothetical launch dates for Teva and Apotex.

D. *Defendant's expert witnesses*

(1) Mr. W. Neil **Palmer**

Mr. W. Neil Palmer was qualified by the Court as a pharmaceutical industry consultant with expertise in formulary listing, market access, reimbursement policies and pricing regimes of the Canadian pharmaceutical marketplace. Mr. Palmer's report in-chief and his responding statement were taken as read. In his testimony, Mr. Palmer provided opinions on the actual ramipril marketplace following genericization; the dates various generic ramipril manufacturers would have gained formulary listing; and the price at which generic manufacturers' ramipril would have been sold in various hypothetical scenarios.

(2) Dr. Robert C. **Carbone**

Dr. Robert C. Carbone was qualified by the Court as a pharmaceutical industry consultant with expertise in forecasting methods, data analysis, quantitative economics, and forecasting for pharmaceutical markets. Dr. Carbone's reports were taken as read. In his testimony, Dr. Carbone provided opinions on the impact of genericization on the ramipril market; erosion curves; the difference between a time series approach and an econometric model; market share allocation in the hypothetical scenarios; and the equivalent factory EUTRxs that would have been realized by each generic manufacturer and Sanofi in a "but for" world.

(3) Ms. Paula **Frederick**

Ms. Paula Frederick was qualified by the Court as a chartered accountant and chartered business valuator with expertise in business valuation and damages quantification. Ms. Frederick opined on the calculation of lost business value and several other aspects of Ms. Loomer's calculations.

(4) Dr. Peter James **Lin**

Dr. Peter James Lin was qualified by the Court as a physician and a Director at the Canadian Heart Research Centre, with expertise in the practice of family/general medicine, including the treatment of cardiovascular diseases. The Court accepted Dr. Lin's report as read. Dr. Lin testified regarding the effect of the HOPE study; his prescribing practices with respect to ramipril; and the indications for Novo-ramipril.

(5) Dr. Iain M. **Cockburn**

Dr. Iain M. Cockburn was qualified by the Court as an economist with expertise in pharmaceutical marketplaces. The Court accepted Dr. Cockburn's reports as read. In his testimony, Dr. Cockburn provided opinions on the pharmaceutical market, including provincial pricing regimes. Dr. Cockburn also discussed Dr. Anis's estimation of market shares and Dr. Carbone's forecast.

(6) Mr. Ross **Hamilton**

Mr. Ross Hamilton was qualified by the Court as a chartered accountant with expertise in investigative and forensic accounting and the quantification of damages. The Court accepted Mr. Hamilton's reports as read. Mr. Hamilton opined on the quantification of Teva's losses, particularly as compared to Ms. Loomer's analysis.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1161-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION AND SANOFI-AVENTIS DEUTSCHLAND GmbH v TEVA CANADA LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	January 16, 17, 18, 19, 20, 2012; January 23, 24, 25, 26, 27, 2012; January 30, 31, 2012; and February 1, 2, 6, 2012
PUBLIC REASONS FOR JUDGMENT:	SNIDER J.
DATED:	MAY 23, 2012

APPEARANCES:

Mr. Gunars A. Gaikis Mr. J. Sheldon Hamilton Mr. Andrew Mandlsohn Mr. Jordan D. Scopa Mr. Jeremy E. Want Mr. Daniel S. Davies	FOR THE PLAINTIFFS/ DEFENDANTS BY COUNTERCLAIM
Mr. Jonathan Stainsby Mr. Mark Davis Mr. Ben Wallwork Mr. Bill Mayo	FOR THE DEFENDANT/ PLAINTIFF BY COUNTERCLAIM

SOLICITORS OF RECORD:

Smart & Biggar Barristers and Solicitors Toronto, Ontario	FOR THE PLAINTIFFS/ DEFENDANTS BY COUNTERCLAIM
Heenan Blaikie LLP Barristers and Solicitors Toronto, Ontario	FOR THE DEFENDANT/ PLAINTIFF BY COUNTERCLAIM